

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE
 in its capacity as elected Office

Date of mailing (day/month/year) 22 February 2001 (22.02.01)	
International application No. PCT/US00/12773	Applicant's or agent's file reference 49386-PCT
International filing date (day/month/year) 10 May 2000 (10.05.00)	Priority date (day/month/year) 10 May 1999 (10.05.99)
Applicant CARL, Allen et al	

1. The designated Office is hereby notified of its election made:

in the demand filed with the International Preliminary Examining Authority on:

 07 December 2000 (07.12.00)

in a notice effecting later election filed with the International Bureau on:

2. The election was
 was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Kiwa Mpay
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference (if desired) (12 characters maximum) 49386-PCT

Box No. I TITLE OF INVENTION SYSTEMS AND METHODS FOR SPINAL FIXATION	
Box No. II APPLICANT	
Name and address: <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)</i>	
HIGHGATE ORTHOPEDICS, INC. One Walnut Street Boston, Massachusetts 02109 United States of America	
<input type="checkbox"/> This person is also inventor.	
Telephone No.	
Facsimile No.	
Teleprinter No.	
State (that is, country) of nationality: US	State (that is, country) of residence: US
This person is applicant for the purposes of: <input type="checkbox"/> all designated States <input checked="" type="checkbox"/> all designated States except the United States of America <input type="checkbox"/> the United States of America only <input type="checkbox"/> the States indicated in the Supplemental Box	
Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)	
Name and address: <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)</i>	
CARL, Allen 308 Highgate Drive Slingerlands, New York 12159 United States of America	
This person is: <input type="checkbox"/> applicant only <input checked="" type="checkbox"/> applicant and inventor <input type="checkbox"/> inventor only <i>(If this check-box is marked, do not fill in below.)</i>	
State (that is, country) of nationality: US	State (that is, country) of residence: US
This person is applicant for the purposes of: <input type="checkbox"/> all designated States <input type="checkbox"/> all designated States except the United States of America <input checked="" type="checkbox"/> the United States of America only <input type="checkbox"/> the States indicated in the Supplemental Box	
<input checked="" type="checkbox"/> Further applicants and/or (further) inventors are indicated on a continuation sheet.	
Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE	
The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: <input checked="" type="checkbox"/> agent <input type="checkbox"/> common representative	
Name and address: <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)</i>	
CORLESS, Peter F. DIKE, BRONSTEIN, ROBERTS & CUSHMAN, LLP 130 Water Street Boston, Massachusetts 02109 United States of America	
Telephone No. (617) 523-3400	
Facsimile No. (617) 523-6440	
Teleprinter No.	
<input type="checkbox"/> Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.	

TRANSMITTAL LETTER TO THE UNITED STATES RECEIVING OFFICE

Date	10 May 2000
International Application No.	
Attorney Docket No.	49386-PCT

I. Certification under 37 CFR 1.10 (if applicable)

EL180585505US
Express Mail mailing number

10 May 2000
Date of Deposit

I hereby certify that the application/correspondence attached hereto is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Assistant Commissioner for Patents, Washington, D.C. 20231.

<i>Susan M. Dillon</i>
Signature of person mailing correspondence

Susan M. Dillon
Typed or printed name of person mailing correspondence

II. New International Application

TITLE	SYSTEMS AND METHODS FOR SPINAL FIXATION
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Earliest priority date (Day/Month/Year)
10 May 1999

SCREENING DISCLOSURE INFORMATION: In order to assist in screening the accompanying international application for purposes of determining whether a license for foreign transmittal should and could be granted and for other purposes, the following information is supplied. (Note: check as many boxes as apply):

- A. The invention disclosed was **not** made in the United States.
- B. There is no prior U.S. application relating to this invention.
- C. The following prior U.S. application(s) contain subject matter which is related to the invention disclosed in the attached international application. (NOTE: priority to these applications may or may not be claimed on form PCT/RO/101 (Request) and this listing does not constitute a claim for priority).

application no.	60/133,356	filed on	10 May 1999
application no.	09/536,732	filed on	28 March 2000

- D. The present international application is identical contains less subject matter than that found in the prior U.S. application(s) identified in paragraph C.
- E. The present international application contains additional subject matter not found in the prior U.S. application(s) identified in paragraph C. above. The additional subject matter is found on pages throughout the application and DOES NOT ALTER MIGHT BE CONSIDERED TO ALTER the general nature of the invention in a manner which would require the U.S. application to have been made available for inspection by the appropriate defense agencies under 35 U.S.C. 181 and 37 CFR 5.1. See 37 CFR 5.15

III. A Response to an Invitation from the RO/US. The following document(s) is (are) enclosed:

- A. A Request for An Extension of Time to File a Response
- B. A Power of Attorney (General or Regular)
- C. Replacement pages:

pages		of the request (PCT/RO/101)	pages		of the figures
pages		of the description	pages		of the abstract
pages		of the claims			

- D. Submission of Priority Documents

Priority document		Priority document	
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- E. Fees as specified on attached Fee Calculation sheet form PCT/RO/101 annex

IV. A Request for Rectification under PCT 91 A Petition A Sequence Listing Diskette

V. Other (please specify):

The person signing this form is the:	<input type="checkbox"/> Applicant	William J. Daley, Jr.
	<input checked="" type="checkbox"/> Attorney/Agent (Reg. No.) 35,487	Typed name of signer
	<input type="checkbox"/> Common Representative	<i>William J. Daley, Jr.</i> Signature

Continuation of Box No. III FURTHER APPLICANTS AND/OR (FURTHER) INVENTOR(S)	
<i>If none of the following sub-boxes is used, this sheet is not to be included in the request.</i>	
<p>Name and address: <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)</i></p> <p>HART, Rickey D. 11 Hillsdale Road Plainville, Massachusetts 02762 United States of America</p>	<p>This person is:</p> <p><input type="checkbox"/> applicant only</p> <p><input checked="" type="checkbox"/> applicant and inventor</p> <p><input type="checkbox"/> inventor only <i>(If this check-box is marked, do not fill in below.)</i></p>
State <i>(that is, country)</i> of nationality: US	State <i>(that is, country)</i> of residence: US
<p>This person is applicant for the purposes of: <input type="checkbox"/> all designated States <input type="checkbox"/> all designated States except the United States of America <input checked="" type="checkbox"/> the United States of America only <input type="checkbox"/> the States indicated in the Supplemental Box</p>	
<p>Name and address: <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)</i></p> <p>WINKLER, Josef K. 2318 Gring Drive Reading, Pennsylvania 19609 United States of America</p>	<p>This person is:</p> <p><input type="checkbox"/> applicant only</p> <p><input checked="" type="checkbox"/> applicant and inventor</p> <p><input type="checkbox"/> inventor only <i>(If this check-box is marked, do not fill in below.)</i></p>
State <i>(that is, country)</i> of nationality: US	State <i>(that is, country)</i> of residence: US
<p>This person is applicant for the purposes of: <input type="checkbox"/> all designated States <input type="checkbox"/> all designated States except the United States of America <input checked="" type="checkbox"/> the United States of America only <input type="checkbox"/> the States indicated in the Supplemental Box</p>	
<p>Name and address: <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)</i></p>	<p>This person is:</p> <p><input type="checkbox"/> applicant only</p> <p><input type="checkbox"/> applicant and inventor</p> <p><input type="checkbox"/> inventor only <i>(If this check-box is marked, do not fill in below.)</i></p>
State <i>(that is, country)</i> of nationality:	State <i>(that is, country)</i> of residence:
<p>This person is applicant for the purposes of: <input type="checkbox"/> all designated States <input type="checkbox"/> all designated States except the United States of America <input type="checkbox"/> the United States of America only <input type="checkbox"/> the States indicated in the Supplemental Box</p>	
<p>Name and address: <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)</i></p>	<p>This person is:</p> <p><input type="checkbox"/> applicant only</p> <p><input type="checkbox"/> applicant and inventor</p> <p><input type="checkbox"/> inventor only <i>(If this check-box is marked, do not fill in below.)</i></p>
State <i>(that is, country)</i> of nationality:	State <i>(that is, country)</i> of residence:
<p>This person is applicant for the purposes of: <input type="checkbox"/> all designated States <input type="checkbox"/> all designated States except the United States of America <input type="checkbox"/> the United States of America only <input type="checkbox"/> the States indicated in the Supplemental Box</p>	
<p><input type="checkbox"/> Further applicants and/or (further) inventors are indicated on another continuation sheet.</p>	

Box No.V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) (mark the applicable check-boxes; at least one must be marked):

Regional Patent

- AP** ARIPO Patent: GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SL Sierra Leone, SZ Swaziland, TZ United Republic of Tanzania, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- EA** Eurasian Patent: AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian
- EP** European Patent: AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- OA** OAPI Patent: BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT (if other kind of protection or treatment desired, specify on dotted line)

National Patent (if other kind of protection or treatment desired, specify on dotted line):

- | | |
|------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <input checked="" type="checkbox"/> AE United Arab Emirates | <input checked="" type="checkbox"/> LR Liberia |
| <input checked="" type="checkbox"/> AL Albania | <input checked="" type="checkbox"/> LS Lesotho |
| <input checked="" type="checkbox"/> AM Armenia | <input checked="" type="checkbox"/> LT Lithuania |
| <input checked="" type="checkbox"/> AT Austria | <input checked="" type="checkbox"/> LU Luxembourg |
| <input checked="" type="checkbox"/> AU Australia | <input checked="" type="checkbox"/> LV Latvia |
| <input checked="" type="checkbox"/> AZ Azerbaijan | <input checked="" type="checkbox"/> MA Morocco |
| <input checked="" type="checkbox"/> BA Bosnia and Herzegovina | <input checked="" type="checkbox"/> MD Republic of Moldova |
| <input checked="" type="checkbox"/> BB Barbados | <input checked="" type="checkbox"/> MG Madagascar |
| <input checked="" type="checkbox"/> BG Bulgaria | <input checked="" type="checkbox"/> MK The former Yugoslav Republic of Macedonia |
| <input checked="" type="checkbox"/> BR Brazil | <input checked="" type="checkbox"/> MN Mongolia |
| <input checked="" type="checkbox"/> BY Belarus | <input checked="" type="checkbox"/> MW Malawi |
| <input checked="" type="checkbox"/> CA Canada | <input checked="" type="checkbox"/> MX Mexico |
| <input checked="" type="checkbox"/> CH and LI Switzerland and Liechtenstein | <input checked="" type="checkbox"/> NO Norway |
| <input checked="" type="checkbox"/> CN China | <input checked="" type="checkbox"/> NZ New Zealand |
| <input checked="" type="checkbox"/> CR Costa Rica | <input checked="" type="checkbox"/> PL Poland |
| <input checked="" type="checkbox"/> CU Cuba | <input checked="" type="checkbox"/> PT Portugal |
| <input checked="" type="checkbox"/> CZ Czech Republic | <input checked="" type="checkbox"/> RO Romania |
| <input checked="" type="checkbox"/> DE Germany | <input checked="" type="checkbox"/> RU Russian Federation |
| <input checked="" type="checkbox"/> DK Denmark | <input checked="" type="checkbox"/> SD Sudan |
| <input checked="" type="checkbox"/> DM Dominica | <input checked="" type="checkbox"/> SE Sweden |
| <input checked="" type="checkbox"/> EE Estonia | <input checked="" type="checkbox"/> SG Singapore |
| <input checked="" type="checkbox"/> ES Spain | <input checked="" type="checkbox"/> SI Slovenia |
| <input checked="" type="checkbox"/> FI Finland | <input checked="" type="checkbox"/> SK Slovakia |
| <input checked="" type="checkbox"/> GB United Kingdom | <input checked="" type="checkbox"/> SL Sierra Leone |
| <input checked="" type="checkbox"/> GD Grenada | <input checked="" type="checkbox"/> TJ Tajikistan |
| <input checked="" type="checkbox"/> GE Georgia | <input checked="" type="checkbox"/> TM Turkmenistan |
| <input checked="" type="checkbox"/> GH Ghana | <input checked="" type="checkbox"/> TR Turkey |
| <input checked="" type="checkbox"/> GM Gambia | <input checked="" type="checkbox"/> TT Trinidad and Tobago |
| <input checked="" type="checkbox"/> HR Croatia | <input checked="" type="checkbox"/> TZ United Republic of Tanzania |
| <input checked="" type="checkbox"/> HU Hungary | <input checked="" type="checkbox"/> UA Ukraine |
| <input checked="" type="checkbox"/> ID Indonesia | <input checked="" type="checkbox"/> UG Uganda |
| <input checked="" type="checkbox"/> IL Israel | <input checked="" type="checkbox"/> US United States of America |
| <input checked="" type="checkbox"/> IN India | <input checked="" type="checkbox"/> continuation-in-part |
| <input checked="" type="checkbox"/> IS Iceland | <input checked="" type="checkbox"/> UZ Uzbekistan |
| <input checked="" type="checkbox"/> JP Japan | <input checked="" type="checkbox"/> VN Viet Nam |
| <input checked="" type="checkbox"/> KE Kenya | <input checked="" type="checkbox"/> YU Yugoslavia |
| <input checked="" type="checkbox"/> KG Kyrgyzstan | <input checked="" type="checkbox"/> ZA South Africa |
| <input checked="" type="checkbox"/> KP Democratic People's Republic of Korea | <input checked="" type="checkbox"/> ZW Zimbabwe |
| <input checked="" type="checkbox"/> KR Republic of Korea | Check-boxes reserved for designating States which have become party to the PCT after issuance of this sheet: |
| <input checked="" type="checkbox"/> KZ Kazakhstan | <input checked="" type="checkbox"/> AG .. Antigua and Barbuda |
| <input checked="" type="checkbox"/> LC Saint Lucia | <input checked="" type="checkbox"/> DZ .. Algeria |
| <input checked="" type="checkbox"/> LK Sri Lanka | |

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. (Confirmation (including fees) must reach the receiving Office within the 15-month time

Supplemental Box *If the Supplemental Box is not used, this sheet need not be included in the request.*

1. *If, in any of the Boxes, the space is insufficient to furnish all the information: in such case, write "Continuation of Box No. ..." [indicate the number of the Box] and furnish the information in the same manner as required according to the captions of the Box in which the space was insufficient, in particular:*

- (i) *if more than two persons are involved as applicants and/or inventors and no "continuation sheet" is available: in such case, write "Continuation of Box No. III" and indicate for each additional person the same type of information as required in Box No. III. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below;*
- (ii) *if, in Box No. II or in any of the sub-boxes of Box No. III, the indication "the States indicated in the Supplemental Box" is checked: in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the applicant(s) involved and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is applicant;*
- (iii) *if, in Box No. II or in any of the sub-boxes of Box No. III, the inventor or the inventor/applicant is not inventor for the purposes of all designated States or for the purposes of the United States of America: in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the inventor(s) and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is inventor;*
- (iv) *if, in addition to the agent(s) indicated in Box IV, there are further agents: in such case, write "Continuation of Box No. IV" and indicate for each further agent the same type of information as required in Box No. IV;*
- (v) *if, in Box No. V, the name of any State (or OAPI) is accompanied by the indication "patent of addition," or "certificate of addition," or if, in Box No. V, the name of the United States of America is accompanied by an indication "continuation" or "continuation-in-part": in such case, write "Continuation of Box No. V" and the name of each State involved (or OAPI), and after the name of each such State (or OAPI), the number of the parent title or parent application and the date of grant of the parent title or filing of the parent application;*
- (vi) *if, in Box No. VI, there are more than three earlier applications whose priority is claimed: in such case, write "Continuation of Box No. VI" and indicate for each additional earlier application the same type of information as required in Box No. VI;*
- (vii) *if, in Box No. VI, the earlier application is an ARIPO application: in such case, write "Continuation of Box No. VI", specify the number of the item corresponding to that earlier application and indicate at least one country party to the Paris Convention for the Protection of Industrial Property or one Member of the World Trade Organization for which that earlier application was filed.*

2. *If, with regard to the precautionary designation statement contained in Box No. V, the applicant wishes to exclude any State(s) from the scope of that statement: in such case, write "Designation(s) excluded from precautionary designation statement" and indicate the name or two-letter code of each State so excluded.*

3. *If the applicant claims, in respect of any designated Office, the benefits of provisions of the national law concerning non-prejudicial disclosures or exceptions to lack of novelty: in such case, write "Statement concerning non-prejudicial disclosures or exceptions to lack of novelty" and furnish that statement below.*

CONTINUATION OF BOX IV:

CONLIN, David G.
 NEUNER, George W.
 BUCKLEY, Linda M.
 MANUS, Peter J.
 DALEY, Jr., William J.
 LOWEN, Cara Z.
 BUCHANAN, Robert L.
 O'DAY, Christine C.
 TUCKER, David A.
 HARTNELL, George

The above-identified attorneys are all members of the firm Dike, Bronstein, Roberts & Cushman, LLP, located at 130 Water Street, Boston, Massachusetts 02109, USA.

CONTINUATION OF BOX V:

This application is a continuation-in-part of U.S.S.N. 09/536,732 filed on March 28, 2000 which claims the benefit of U.S. Provisional Serial No. 60/133,356 filed on May 10, 1999.

Box No. VI PRIORITY CLAIM		<input type="checkbox"/> Further priority claims are indicated in the Supplemental Box.		
Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is:		
		national application: country	regional application: * regional Office	international application: receiving Office
item (1) 28 March 2000 (28/03/00)	09/536,732	US		
item (2) 10 May 1999 (10/05/99)	60/133,356	US		
item (3)				
<input checked="" type="checkbox"/> The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) (only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office) identified above as item(s): <u>(1) and (2)</u> <small>* Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.</small>				

Box No. VII INTERNATIONAL SEARCHING AUTHORITY	
Choice of International Searching Authority (ISA) <small>(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):</small> ISA/ US	Request to use results of earlier search; reference to that search <small>(if an earlier search has been carried out by or requested from the International Searching Authority):</small> Date (day/month/year) Number Country (or regional Office)

Box No. VIII CHECK LIST: LANGUAGE OF FILING	
This international application contains the following number of sheets: request : 5 description (excluding sequence listing part) : 35 claims : 13 abstract : 1 drawings : 16 sequence listing part of description : 0 Total number of sheets : 70	This international application is accompanied by the item(s) marked below: 1. <input checked="" type="checkbox"/> fee calculation sheet 2. <input type="checkbox"/> separate signed power of attorney 3. <input type="checkbox"/> copy of general power of attorney; reference number, if any: 4. <input type="checkbox"/> statement explaining lack of signature 5. <input type="checkbox"/> priority document(s) identified in Box No. VI as item(s): 6. <input type="checkbox"/> translation of international application into (language): 7. <input type="checkbox"/> separate indications concerning deposited microorganism or other biological material 8. <input type="checkbox"/> nucleotide and/or amino acid sequence listing in computer readable form 9. <input type="checkbox"/> other (specify):
Figure of the drawings which should accompany the abstract:	Language of filing of the international application: English

Box No. IX SIGNATURE OF APPLICANT OR AGENT	
Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).	
For Highgate Orthopedics, Inc.	Allen Carl _____
	Ricky D. Hart _____
Name: _____	Josef K. Winkler _____
Title: _____	

For receiving Office use only	
1. Date of actual receipt of the purported international application:	2. Drawings: <input type="checkbox"/> received: <input type="checkbox"/> not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:	
4. Date of timely receipt of the required corrections under PCT Article 11(2):	
5. International Searching Authority (if two or more are competent): ISA/	6. <input type="checkbox"/> Transmittal of search copy delayed until search fee is paid.

For International Bureau use only
Date of receipt of the record copy by the International Bureau:

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty and of the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the letter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended ?

The claims only.

The description and the drawings may only be amended during international preliminary examination under Chapter II.

When ? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments ?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How ? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

What documents must/may accompany the amendments ?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confounded with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

NOTES TO FORM PCT/ISA/220 (continued)

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 4(4))

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

The statement should be brief, it should not exceed 500 words if in English or if translated into English.

It should not be confounded with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It should not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

In what language?

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Consequence if a demand for international preliminary examination has already been filed?

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a) first sentence).

Consequence with regard to translation of the international application for entry into the national phase?

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

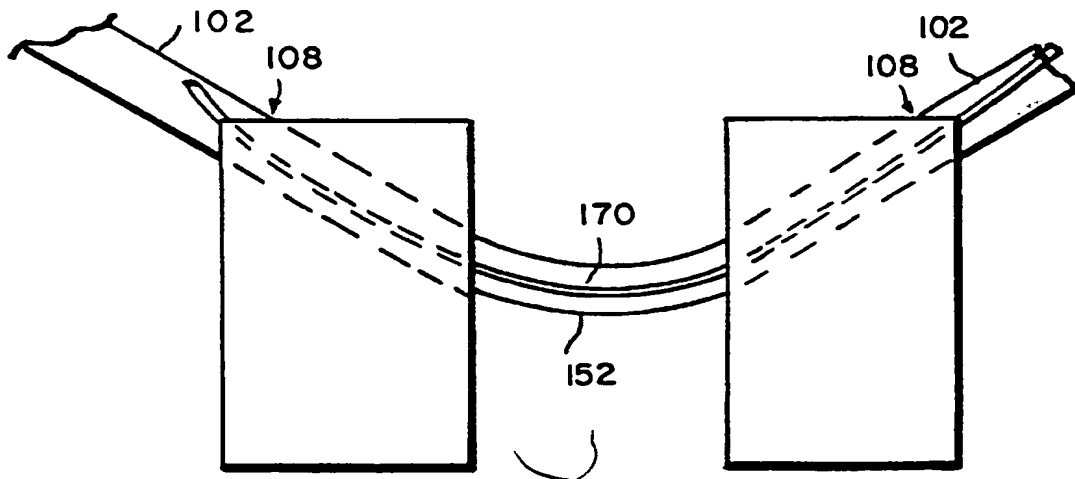
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<p>(21) International Application Number: PCT/US00/12773</p> <p>(22) International Filing Date: 10 May 2000 (10.05.00)</p> <p>(30) Priority Data: 60/133,356 10 May 1999 (10.05.99) US 09/536,732 28 March 2000 (28.03.00) US</p> <p>(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application US 09/536,732 (CIP) Filed on 28 March 2000 (28.03.00)</p> <p>(71) Applicant (for all designated States except US): HIGHGATE ORTHOPEDICS, INC. [US/US]; One Walnut Street, Boston, MA 02109 (US).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): CARL, Allen [US/US]; 308 Highgate Drive, Slingerlands, NY 12159 (US). HART, Rickey, D. [US/US]; 11 Hillsdale Road, Plainville, MA 02762 (US). WINKLER, Josef, K. [US/US]; 2318 Gring Drive, Reading, PA 19609 (US).</p>	<p>(74) Agents: CORLESS, Peter, F. et al.; Dike, Bronstein, Roberts & Cushman, LLP, 130 Water Street, Boston, MA 02109 (US).</p> <p>(81) Designated States: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>	

(54) Title: SYSTEMS AND METHODS FOR SPINAL FIXATION



(57) Abstract

Featured are a method, and apparatus for fixing adjacent vertebrae of a spine that avoids the need, associated problems with prior cage or straight rod and screw systems. Methods and apparatus of the invention utilize a new implant member (160), which preferably is arcuate. Preferred methods of the invention for stabilizing adjacent vertebrae of the spine, include steps of providing a positioning apparatus (100) including two guide sleeves (102), each guide sleeve (102) having a long axis, and locating the two guide sleeves (102) with respect to the adjacent vertebrae such that a vertex formed by the long axis of each guide sleeve (102) is located in the intervertebral space for the adjacent vertebrae. The method further includes forming an aperture in each of the adjacent vertebrae so that the implant (160) extends between the adjacent vertebrae, and through the intervertebral space.

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SYSTEMS AND METHODS FOR SPINAL FIXATION

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This application claims the benefit of U.S. Provisional Application Serial No. 60/133,356 filed May 10, 1999, and of U.S. application serial number 09/536,732, filed March 28, 2000, which applications are incorporated herein by reference in their entirety.

10

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention generally relates to methods, systems and apparatuses for bony fixation, more particularly to methods, systems and apparatuses adapted for fixing the bones of the spine, and to methods, systems and apparatuses adapted for securing a prosthetic device within the bones of the human body, more specifically securing a prosthetic device within the bones of the spine.

15

2. Background of the Invention.

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Fixation or fusion of vertebral columns with bone or material, rods or plates is a common, long practiced surgical method for treating a variety of conditions. Many of the existing procedures involve the use of components that protrude outwardly, which may contact and damage a body part, such as the aorta, the vena cava, the sympathetic nerves, the lungs, the esophagus, the intestine and the ureter. Also, many constructions involve components that may loosen and cause undesirable problems, often necessitating further surgical intervention. Additionally, limiting the success of these procedures are the bio-mechanical features of the spine itself, whose structure must simultaneously provide support to regions of the body, protect the vertebral nervous system and permit motion in multiple planes.

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As indicated above, spinal surgery for spine fusion generally involves using implants and instrumentation to provide support to the affected area of the spine while allowing the bones thereof to fuse. The technology initially evolved using bone chips around and on top of an area of the spine that had been roughened to simulate a fracture in its consistency. The area, having encountered the bone chips, would then proceed to heal like a fracture, incorporating the bone chips. However, surgical procedures dealing with the spine present notable challenges. For example, bioengineers have been required to identify the various elements of the complex motions that the spine performs, and the components of the complex forces it bears. This complexity has made it difficult to achieve adequate stability and effective healing in surgical procedures directed to the spine.

One surgical technique provided by Cloward, involves cutting a dowel type hole with a saw across or through the moveable intervertebral disc and replacing it with a bone graft that was harvested from the hip bone. This procedure limits motion and mobility and results in a fusion of the adjacent vertebral bodies. However, as a result of the complex motions of the spine, it is often difficult to secure the dowel from displacing. Further, it has become apparent over time, however, that this particular technique does not always yield a secure fusion.

Other techniques have been developed that involve the placement of various hardware elements, including rods and hooks, rods and screws and plates and screws. The dowel technique also has advanced over the past five years or so, with dowels being fabricated from cadaver bone or metals such as titanium or stainless steel. These techniques, whether using hardware, dowels or some combination thereof, have a common goal to enhance stability by diminishing movement, thereby resulting in or enhancing the potential of a fusion of adjacent vertebral bones. For example, in one of these other techniques, the disc is removed and adjacent vertebrae are positioned in a stable position by placing a plate against and traversing them, which plate is secured or anchored to each by means of screws.

In another procedure, cages in the form of two parallel circular or rectangular devices are made out of a material such as titanium or stainless steel and these devices are fenestrated. Bone is packed in the center of the devices that will heal to adjacent bone through each fenestration. In this procedure, the disc space is distracted so all
5 ligamentous structures are taut and the bones are held in their normal maximal position of distraction. Because the cages are implanted in spongy bone, they are more likely to collapse the surrounding bone, thus resulting in loss of distraction and subsequently cage dislodgment.

10 U.S. Patent 5,591,235 reports a certain spinal fixation device and technique for stabilizing vertebrae. In this technique, a hollow screw is inserted into a hole, preferably a hole saw recess, in each adjoining vertebrae. A channel is cut into the vertebrae, which is lined up with corresponding axial slots in the screw. A rod is
15 inserted into the channel and so as to pass through the axial slots in the screw. The rod is secured to each of the screws by means of a locking cap. The rod also is arranged so as to provide a bridge between the hollow screws in the adjoining vertebrae. Certain disadvantages have been surmised using such a device and technique. For example, it has become apparent that the trough in the vertebral bodies destabilizes some of the cortex of the vertebrae body wall, which is the strongest
20 component.

In addition to fixation or fusion of vertebral columns, the prior art also describes methods or other spinal repair procedures, such as discectomy wherein an
25 artificial disc or prosthetic device is placed within the vertebrae of the spine. For such prior art methods and related devices, there have been short comings such as having difficulty in securing the prostheses within the vertebral space or resulting in significant modification or damage to the load bearing surfaces of the vertebrae in an effort to secure the prosthesis.

30 Thus, it would be desirable to provide a new apparatus, system and methods for spinal fixation that enhances healing of the bone while providing structural support

to the spine. It would be particularly desirable to provide such an apparatus, system and method that would involve the use of open surgical or minimally invasive surgical techniques as well as a technique in which the implant burrows in the bone spine, traverses across the disk space, and ends in an adjacent or neighboring vertebrae or
5 vertebrae, providing limited or no protrusions. It also would be desirable to provide such an apparatus, system and method where the implant is retained within the bone without requiring contour-varying external vertebral wall fixation as compared to conventional devices, as such a device would avoid many of the problems associated with conventional devices such as blood vessel injury, erosion into organs, as well as
10 placement near nerves. Additionally, it would be desirable to provide such an apparatus, system and method where the implant is retained within the bone and is utilized to secure an artificial prosthesis for example within the vertebral bodies. Such securing is accomplished with or without the use of the annulus, and without insult to portions of the vertebral surfaces bearing significant loading.

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SUMMARY OF THE INVENTION

I have now found new methods and apparatus for fixing adjacent vertebrae of a spine. The methods and apparatus of the invention utilize a new implant member, which preferably is arcuate, and avoids the associated problems with prior cage or
20 straight rod and screw systems. It is within the scope of the present invention for the implant member to have any geometric shape or configuration consistent with the intended use including a straight member.

Preferred methods of the invention for stabilizing adjacent vertebrae of the
25 spine, include the steps of providing a positioning apparatus including two guide sleeves, each guide sleeve having a long axis and locating the two guide sleeves with respect to the adjacent vertebrae such that a vertex formed by the long axis of each guide sleeve is located in the intervertebral space for the adjacent vertebrae. The method further includes forming an aperture in each of the adjacent vertebrae using
30 the guide sleeves and inserting an implant into the apertures formed in each of the

adjacent vertebrae so that the implant extends between the adjacent vertebrae and through the intervertebral space.

5 Preferably, the aperture formed in the vertebrae is arcuate and the implant being inserted also is arcuate. The arcuate aperture in each vertebrae can be suitably formed by drilling or other ablation. More particularly, an initial aperture can be drilled in each of the adjacent vertebrae to create intersecting apertures with convergent paths within the intervertebral space; and the initial aperture then enlarged to receive the implant. That enlarging of the initial aperture can be suitably performed
10 by a variety of procedures, e.g. by using a drill bit, a reamer, an awl, impaction drill, shape memory coring device, or curved coring device, or the like.

The step of forming an aperture also can further include inserting a guide member, after drilling of the initial aperture, into one of the guide sleeves, down
15 through the initial aperture in one adjacent vertebrae, through the intervertebral space and into the initial aperture in the other adjacent vertebrae; and advancing an aperture enlarging device over the guide member so as to enlarge the initial aperture. In this case, the aperture enlarging device is suitably a curved reamer or a curved drill bit, and the curved reamer or the curved drill bit is advanced over the guide member so as
20 to form an arcuate aperture in each of the adjacent vertebrae. It also should be appreciated that multiple vertebral holes can be created using the same methods as disclosed herein. In that manner, multiple arcuate implants can be placed, e.g. if greater mechanical stability is considered desirable.

25 The positioning apparatus can further include a cross member and an intervertebral spacer, preferably where the guide sleeves are pivotally mounted to the cross member and the intervertebral spacer is spaced from the cross member and interconnected thereto at about a mid point between the pivot points for the guide sleeves. In this case, the stabilizing method can further include locating the
30 intervertebral spacer in the intervertebral space between the adjacent vertebrae; and maintaining alignment of the guide sleeves with respect to the adjacent vertebrae so

that a consistent angle is maintained between the guide sleeve and the vertebrae during at least a portion of said forming of the aperture. The intervertebral spacer also can be configured so as to provide protection to the spine during the drilling when disposed in the intervertebral space.

5

In an alternative embodiment, the positioning system being provided includes a cutter bracket system and a curved drilling sub-system affixed thereto. The cutter bracket system includes a pivot arm whose pivot point is disposed between the adjacent vertebrae opposite the intervertebral space. More particularly, the pivot point is at about the midpoint between the adjacent vertebrae. The curved drilling sub-system is affixed to the pivot arm such that as the pivot arm rotates about the pivot point the curved drill sub-system follows an established cutting path. In a more specific embodiment, the drilling sub-system is affixed proximal or at the distal end of the pivot arm. The positioning apparatus according to the alternative embodiment can further include a mechanism that temporarily secures the cutter bracket system to the adjacent vertebra to be fused and which positions and maintains the pivot point at the desired location. Also, the curved drill subsystem can include a curved cannula, a flexible member running through the curved cannula and a cutting burr secured to an end of the flexible member.

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As to the step of forming an aperture using a positioning system according to the alternative embodiment, this step includes rotating the pivot arm in one direction about the pivot point so the curved drilling sub-system forms an aperture in one of the adjacent vertebrae and rotating the pivot arm in another direction about the pivot point so as to form an aperture in the other of the adjacent vertebrae. In a more specific embodiment, the step of forming further includes remounting the curved drilling subsystem to the pivot arm before rotating the pivot arm in the another direction so a cutting element of the curved drilling subsystem is aligned for the direction of movement.

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As to inserting the implant, the method step includes successively drawing a portion of the implant through the arcuate aperture in one adjacent vertebrae, through the intervertebral space and into the arcuate aperture of the other adjacent vertebrae. In a specific embodiment, the step of inserting includes securing one end of a guide
5 wire to an end of the implant; passing a free end of the guide wire through the arcuate aperture in one of the adjacent vertebrae, through the intravertebral space and through the arcuate aperture in the other adjacent vertebrae; and pulling on the guide wire free end to thereby successively draw the portion of the implant.

10 In another embodiment, the step of inserting includes inserting a beginning end of the implant into an entrance opening of one of the adjacent vertebrae; applying a force to the portion of the implant extending from the entrance opening so as to drive the implant beginning end through the arcuate aperture in the aperture of said one of the adjacent vertebrae, through the intervertebral space and into the arcuate aperture
15 in the other of the adjacent vertebrae.

The implant being inserted into the final aperture is made from one or more of a metal (e.g., titanium or stainless steel), bone, morphogenic protein (including a combination of bone and bone morphogenic protein), carbon fiber composite, nitinol
20 or biodegradable materials such as polyactic acid or polyglycolic acids and copolymers and other derivatives thereof, or collagen and collagen coated metal or bone. The implant also may comprise an in situ-formed plug where the aperture acts as a mold for an epoxy or other polymer-based system. Also, the implant can be solid or hollow and arranged with or without ingrowth fenestrations and screw holes for
25 post-insertion securement. The implant also can be configured so the implant includes a first and a second section, where a distal end of each of the first and second sections is configured so as to be capable of being secured together. For such an implant, the method further includes the steps of inserting the first section into the aperture in one of the adjacent vertebrae so that the distal end therefore is disposed in the
30 intervertebral space; inserting the implant second section into the aperture in one of the adjacent vertebrae so that the distal end therefore is disposed in the intervertebral

space; and securing the distal ends of the first and second sections together. The implant sections being inserted can be arcuate with a radius substantially the same as the arcuate aperture or substantially straight. In particular embodiments, the distal ends of the implant sections are secured to each other by e.g. a nut, bolt, pin, expansion or press-fit device, or interlocking member on the end of each section. Other stabilization methods also can be employed. For instance, a plate can be applied to the vertebrae surface with attachments at each end of the tunnel traversed by an implant in accordance with the invention.

10 Another method of the present invention for stabilizing adjacent vertebrae of the spine includes the step of forming a common channel in and between the adjacent vertebrae and inserting a biscuit implant in the common channel so as to bridge between the adjacent vertebrae. In more specific embodiments, the step of forming includes simultaneously cutting a slot, preferably an arcuate slot, in each of the adjacent vertebrae so as to form the common channel and providing a device
15 configured so as to be capable of simultaneously cutting the slot in each of the adjacent vertebrae. Also for said step of inserting, the biscuit implant can be further configured so as to include a spacer element that is received in the intervertebral space between the adjacent vertebrae when the biscuit is disposed in the common channel.

20 In another alternative aspect of the invention, a discectomy can be performed and a stabilizing wedge (inner) implant inserted between the vertebrae. The wedge (inner tool) establishes lordosis, provides a construction reference, and carries on it the stabilizing wedge implant. Retracted stop-cut blades on the inner tool are then engaged, cutting into the vertebrae in the vertical plane. A hole saw can be used to create a circular cut in the vertebrae to facilitate insertion of the outer implant. Once the cut is complete, the bone harvested in the tubular cutter can be manipulated into the implant. A circular (outer) implant is then inserted over the inner tool. The outer tool then references the position of the inner tool and guides the implant into place.
25 After the two implants nest together along a key and groove, the outer tool is removed. A fenestrated circular member then replaces the outer cutting tool and the
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inner tool is rotated about 90 degrees and then removed. Working together, the two rotated implants capture the vertebral body sections, which are now rotated about 90 degrees and through their many holes, provide blood exchange with the adjacent bone to accomplish fusion.

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Also featured is a system and apparatus embodying the described methods or techniques for internal fixation of the spine.

Other aspects and embodiments of the invention are discussed below.

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BRIEF DESCRIPTION OF THE DRAWING

FIG. 1A is a schematic view of a positioning jig according to the present invention;

FIG. 1B is a front view of the intervertebral spacing member of FIG. 1A;

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FIG. 2A is a schematic view of the positioning jig of FIG. 1A disposed about two vertebral bodies;

FIG. 2B is a schematic view of an alternative positioning jig according to the present invention disposed about two vertebral bodies;

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FIGS. 3A-E are schematic views that illustrate the various steps of the process to form a hole in each vertebral body for implanting a fixating member therein;

FIGS. 4A and 4B are schematic views that illustrate alternate ways of making a hole in each vertebral body;

25

FIG. 4C is a plan view of a Romano device for making a curved hole. Shown is one of the two opposed curved cutter guides and a flexible cable having a cutting bit attached to one end;

FIG. 5A is a schematic view of one device for implanting the fixating member;

FIG. 5B is a schematic view of alternate device for implanting the fixating member;

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FIG. 6A is a schematic view of the vertebral bodies illustrating the implantation of the fixating member in the holes;

FIG. 6B is a schematic view of the vertebral bodies illustrating another form of implantation of the fixating member in the holes particularly for securing an intravertebral prosthetic device;

FIG. 6C is a schematic view of the vertebral bodies to illustrate securing of the
5 fixating member;

FIGS. 7A-C are schematic views of the implantation of a fixating member made from nitinol;

FIGS. 8A-B are exemplary cross sectional views of a guide sleeve including a mechanical guide to guide the nitinol fixating member during insertion;

FIG. 9 is a schematic view of the vertebral bodies with a fixating member
10 according to a second aspect of the present invention;

FIG. 10 is a schematic view of the vertebral bodies with a fixating member according to a third aspect of the present invention;

FIG. 11A is a schematic view of a cutter bracket system according to the
15 present invention;

FIG. 11B is a schematic view of a curved drill used with the cutter bracket system of FIG. 11A;

FIG. 12A is a perspective view of a common channel cutting device according to the present invention;

FIG. 12B is a perspective view of a portion of the channel cutting device of
20 FIG. 12A with the cutting implement extended;

FIG. 12C is a schematic view of the channel cutting device of FIG. 12A disposed on two vertebral bodies;

FIG. 12D is a schematic view of the two vertebral bodies to illustrate the
25 implantation of the biscuit implant in the cut common channel;

FIG. 12E is another view of the two vertebral bodies to illustrate the implantation of the biscuit implant including a spacing element in the cut common channel;

FIG. 12F is a perspective view of the biscuit implant of FIG. 12D;

FIG. 12G is a side view of the biscuit implant with spacing element of FIG.
30 12E;

FIGS. 12H-K are perspective views of various exemplary biscuit implants according to the present invention;

FIGS. 13A-13F illustrate an alternative implant system of the invention; where FIG. 13A is an isometric view of an inner implant, FIG. 13B is an isometric view of an outer implant, FIG. 13C is a lateral view showing a preferred positioning of the implant system, FIG. 13D is an anterior view of the outer implant within which the inner implant is secured, FIG. 13E is an anterior view of the outer and inner implant after rotation, and FIG. 13F is a perspective view of an embodiment of the implant system;

FIG. 14A is a schematic view of an inner tool positioned within the intervertebral disk space;

FIG. 14B is an isometric view of the inner tool;

FIG. 14C is a cross-sectional view of the inner tool, with retracted and extended stop-cut blades;

FIG. 15 is a schematic view of the inner and outer tool system positioned in relation to the vertebral bodies;

FIG. 16 is a schematic view showing bone-to-bone with no gap application; and

FIGS. 17A-C are schematic views of exemplary implants useable for securing a prosthetic device.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to the various figures of the drawing wherein like reference characters refer to like parts, there is shown in FIGS. 1-2 various schematic views of a drill guide or positioning jig 100 that positions or aligns the drill bits before making the holes in each of the vertebral bodies 2. The positioning jig 100 includes two guide sleeves 102, a cross member 104 and an intervertebral spacing member 110. Each guide sleeve 102 preferably is a hollow tubular member having a lumen or passage therein for receiving and guiding the means for forming at least the initial aperture in the adjacent vertebrae such as a drill bit 150 (FIG. 3B). As indicated elsewhere herein, the aperture may be formed using other techniques such as the ablation of bone

by an energy source, e.g., high-pressure water, high-pressure air, ultrasound, or a laser. As such, it shall be understood that the internal sizing and configuration of the guide sleeves is established to accommodate the particular mechanism used for forming the aperture.

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The guide sleeves 102 are mounted to the cross member 104 in such a way that they are each pivotal about the cross member and so each can be secured or locked in a particular angular position with respect to the cross member. Although a single mounting/ pivot point 106 is illustrated, it is within the scope of the present invention for the cross member 104 and each guide sleeve 102 to be configured with a plurality or more of such pivot/ mounting points. In an exemplary embodiment, the cross member 104 and guide sleeves 102 are constructed from stainless steel; and each guide sleeve is pivotally secured to the cross member by screws.

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The distal end 108 of each guide sleeve 102 is configured for mechanically engaging a surface, edge, corner or other surface artifact or feature of the vertebral body 2. In an exemplary embodiment, and as more clearly illustrated in FIG. 3A, the guide sleeve distal end 108 is configured or arranged with a cutout that is designed to accept the corner of the vertebral body 2. Additionally, the cutout area and thus the distal end 108 also are configured with a plurality or more of teeth 107. The teeth 107 are configured and arranged so the teeth bite into the bony surface of the vertebral body when the corner of the vertebral body 2 is received within the cutout area of the guide sleeve distal end 108. Each guide sleeve is suitable about 20 cm in length, although suitable and preferred guide sleeve lengths can vary depending on the method of access.

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The intervertebral spacing member 110 includes an intervertebral spacer 112 and an interconnecting member 114 that mechanically interconnects the cross member 104 and the intervertebral spacer 112. The interconnecting member 114 is secured to or retained by the cross member 104 so as to be maintained in fixed relation with respect to the pivots 106 for both guide sleeves 102. In an exemplary embodiment,

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the interconnecting member 114 is located at about the midpoint of the cross member 104 between the pivots 106. The interconnecting member 114 also is secured to the cross member 104 so the intervertebral spacer 112 is positioned between the distal ends 108 of the guide sleeves 102. More particularly, the interconnecting member
5 114 is positioned so the intervertebral spacer 112 is received within the distended disc space between the adjacent vertebral bodies 2.

In an exemplary embodiment, the interconnecting member 114 is in the form of a rod and the cross member 104 is configured with a through aperture 109 in which
10 the rod is received. This configuration provides a mechanism by which the interconnecting member 114 is put into and maintained in fixed relation with respect to the pivot points 106. It is within the scope of the present invention for the cross member 104 to have any geometric shape, as well as being hollow or solid in construction, that is otherwise consistent for the intended use of the positioning jig
15 100.

The interconnecting member 114 also can be configured so as to prevent rotational motion of the interconnecting member with respect to the through aperture 109. For example, the rod and through aperture 109 may be configured so as to
20 include a flat side in a portion of the circumference for the through aperture and the rod. Alternatively, the through aperture and rod may be arranged with a key and notch arrangement to prevent rotation.

When the guide sleeves 102 are secured to the cross member 104 and each
25 guide sleeve distal end 108 mechanically engages the surface of the vertebral body 2, the guide sleeves are arranged so they maintain a consistent angle with respect to the vertebral body. Additionally, and in combination with the intervertebral spacer 112, this arrangement provides a three-point reference that ensures appropriate angles and alignment are maintained. Additionally, such a configuration establishes a condition
30 whereby the positioning jig 100 locks down on the motion segment of the spine to be stabilized.

The use of the positioning jig 100 in the method of the present invention can be understood from the following discussion with reference to FIGS. 1-6. It shall be understood that as preparation for spinal fixation/ stabilization, the medical personnel (e.g., surgeon) obtains access to the motion segment or structures to be stabilized or fused using any of a number medical/ surgical procedures known to those skilled in the art. In this regard, this would involve such actions as preparing the disc space and performing retraction of vessels, muscles and nerves.

10 In this regard, it should be recognized that the method and positioning jig 100 of the present invention are particularly advantageous when performing a minimally invasive surgical procedure. The minimally invasive procedure can be performed through three holes, each about 1 inch across, in the abdomen and allows for the procedure to be executed without visualizing the vertebrae. Thus, and in contrast to a number of prior procedures, methods of the invention are not limited to an anterior presentation. Such methods of the invention also can be performed through a posterior, posteriolateral or pedicular approach.

20 In addition, when using a nitinol implant, the positioning jig 100 allows the implant to be properly positioned for and during insertion thereof. After gaining access, the surgeon also could scrape out the material from the failed disc or use this disc or its space as a reference point.

25 As preparation, the surgical personnel also select an intervertebral spacing member 110 that is appropriately sized, so it can accommodate the distended disc space. The intervertebral spacer 112 portion of the intervertebral spacing member 110 is inserted into the intervertebral space 4 between the adjacent vertebrae. In this way, the approximate center or mid point of, and the starting point on, the adjacent vertebrae to be fused or stabilized is thereby established or defined.

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The intervertebral spacer allows the surgeon to maintain extremely accurate disk spacing. The intervertebral spacer also protects the spinal cord from accidental drilling or boring. If desired, the spacer can be made of bone and can be made with or without a through hole. The spacer design is suitably based on a construction that facilitates the selected technique for creating an arcuate aperture. An intervertebral spacer that is comprised of bone offers the advantage of being able to remain implanted following the procedure.

Other materials also can be suitably employed to form an intervertebral spacer. The placement of an implant provides a central axis through which a compressible, functional intervertebral disk member can be reliably secured. The artificial disk member suitably can be made from a variety of compressible materials, including e.g. silicon, elastomeric polymers, polyurethanes and copolymers thereof, hydrogels, collagen or bioabsorbables.

Next, the positioning jig 100 is locked down on top of the motion segment to be immobilized, as more clearly shown in FIG. 2. In this regard, the surgical personnel slide the interconnecting member 114 of the intervertebral spacing member 110 into an aperture 109 provided in the cross member 104. In this way, the aperture 109 in the cross member 104 positions the intervertebral spacing member 110 between the distal and proximal ends of the drilling guides 102. Although illustrated as being located in the mid-point, the intervertebral spacing member can be centrally located or offset to either side to enable drilling of holes in the vertebrae laterally against the spine.

Preferably, the aperture 109 in the cross member 104 is configured so as to prevent the cross member 104 or intervertebral spacing member 110 from rotating with respect to each other. For example, a portion of the aperture 109 and a portion of the interconnecting member 114 is flattened so as to pre-define a given orientation. Alternatively, the aperture 109 is configured with a notch or keyway and the

interconnecting member 114 is configured with a key or protrusion that is received in the keyway.

As provided above, the distal end 108 of each guide sleeve 102 is preferably
5 configured so each distal end mechanically engages the surface of the vertebrae 2. In
the illustrated embodiment, the distal end 108 is arranged with a cutout area that is
designed to accept the corner of the vertebrae 2 as more clearly illustrated in FIG. 3.
As also shown in FIG. 3, the cutout area is provided with a plurality of teeth 107 that
bite into the bony surface of the vertebrae 2. It is within the scope of the present
10 invention for the guide sleeve distal end 108 to be disposed at other positions on the
surface of the vertebrae 2 such as that illustrated in FIG. 6A.

After locating the positioning jig 100 with respect to the motion segment to be
fused, the surgical personnel secure the guide sleeves 102 at each of the pivots 106.
15 This advantageously ensures that the appropriate angles and alignment of the guide
sleeves 102 with respect to the vertebrae 2 are maintained as well as locking the
positioning jig 100 down on the motion segment to be fused.

As noted above, an initial through hole is formed in each vertebrae 2 by any of
20 a number of methods, e.g. by a drill, by ablation of the material comprising the
vertebrae using an energy source such as RF, ultrasonic waves, cryogenics and water
jets or by any other means known to those skilled in the art and which can be adapted
for use with the positioning jig 100 of the present invention. For purposes of
describing the present invention, however, the following discussion is simplified to
25 describing the method in terms of drilling the initial aperture or initial through hole 6
in the vertebrae 2. This, however, shall not be inferred as being a limitation on the
method according to the present invention to only drilling.

A fixed or flexible drill bit 150 is inserted into and down each drill guide 102
30 so the ends thereof contact the surface of the vertebrae 2. The surgical personnel
operate the drill bits in accordance with accepted techniques so as to create an initial

through hole 6 in each of the vertebrae. Preferably, and as shown in FIG. 3B, the through holes 6 being created are intersecting with convergent paths within the intervertebral space 4. In other words, the projection of the long axis for each of these through holes 6 intersects so the vertex created by intersection of the long axes is
5 located within the intervertebral space 4.

The initial through hole 6 initially formed in each vertebrae 2 has a diameter much less than that of the implant 160 that is to be used to stabilize or fuse the motion segment. After forming the initial through hole 6, the surgical personnel insert a guide
10 wire 170, such as a 0.093 inch nitinol guide wire, into and down one guide sleeve 102 and through the through hole in one vertebrae 2. The surgical personnel continue to push the guide wire 170 across the intervertebral space 4 and into the through hole 6 in the other vertebrae as more clearly illustrated in FIGS. 3C-D. In a particular embodiment, the guide wire 170 is configured with a slightly curved tip. The guide
15 wire 170 is generally in a curved configuration when disposed in the through hole 6 of the vertebrae 2.

A flexible/curved drill bit 152 is then passed through one of the guide sleeves 102 and over the guide wire 170 so as to form a curved through aperture 6a in each of
20 the vertebrae as shown in FIG. 3E. The curved or arcuate through aperture 6a is formed with a cross-section that complements the cross-sectional shape of the implant 160. Preferably, the arcuate through aperture is sized to be slightly smaller than that of the implant 160 so there is a friction, snug or interference fit between the implant 160 and the arcuate through aperture 6a.

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In this way, when the implant 160 is inserted into the arcuate through aperture 6a, it will remain therein without further need of screws or other artifacts or devices for securing the ends of the implant to each vertebrae 2. It is within the scope of the present invention, however, for screws or other devices be provided as an additional
30 measure or protection for securing the implant 160 within the vertebrae 2.

Alternatively, the curved or arcuate through aperture 6a is formed using any of a number of other techniques as described below. In one case, and as shown in FIG. 4A, the arcuate through aperture 6a is formed in the vertebrae 2 by using a flexible reamer 200. The flexible reamer is run or passed over the guide wire 170 to ream or core out the arcuate through aperture 6a. The cancellous bone of the vertebrae 2 is relatively soft so that it is possible to use a reamer to core the hole aperture. Similarly, and as shown in FIG. 4B, a curved awl or a progressively larger guide wire 170a can be used to punch a curved hole in the vertebrae. FIG. 4C shows a Romano device suitable for drilling a curved bore such as that disclosed in USP 5,700,265 the teachings of which are incorporated herein by reference. A swing arm 830 and curved guide arm 834 navigate the drill bit 840 through a defined radius of curvature.

In addition to the mechanical devices for drilling, punching or reaming out the arcuate through aperture 6a, the discharge end of an energy source, such as RF, ultrasonic, cryogenic, laser and water, can be located within the guide sleeve 102 and passed over the guide wire so as to form the arcuate through aperture. For example, the nozzle(s) of a high pressure water source can be arranged so the discharging or ice crystal water impinges on the bony material of the vertebrae 2 and the material is thereby ablated away to form the arcuate through aperture 6a. Similarly, laser light, RF waves or ultrasonic waves can be focused on the bony material within the vertebrae 2 to form the arcuate through aperture 6a.

The foregoing describes the formation of the arcuate through aperture 6a that receives the implant 160 by passing a mechanism from the entrance to the exit of the initially formed through hole 6. It is within the scope of the present invention, for a guide to be located within the intervertebral space 4 so the curved through aperture is formed by drilling from the intervertebral space out, rather from the outside in.

There is shown in FIG. 2B a schematic view of an alternative positioning jig 100a that is disposed about two vertebral bodies. This alternative positioning jig 100a is similar to the positioning jig 100 of FIG. 2A except for the guide sleeves. As such

reference shall be made to the foregoing discussion regarding FIGS. 1-2A for further details as to the common features for these two positioning jigs 100,100a. In the illustrated embodiment, a guide wire 170 is being inserted into one of the guide sleeves 102a and is configured so that the proximal end of the guide wire 170 is arranged so as to include an impact fitting to protect the guide wire about the proximal end.

In the alternative embodiment, the guide sleeves 102a are tubular members that are configured so that at least a portion 103 of each guide sleeve is arcuate. In the illustrated embodiment, the arcuate portion 103 of the guide sleeve 102a is proximal the vertebral body such that one end of the arcuate portion comprises the distal end 108 of the guide sleeve that is in contact with the vertebral body 2. It is contemplated, however, that the guide sleeve can be configured so as to be substantially arcuate between the vertebral body 2 and the cross member 104.

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The arcuate shape provides a convenient mechanism that can simplify the above-described process for making an arcuate through hole 6a in the vertebral body 2. The arcuate shape also provides a mechanism to orient the tool, device or apparatus being inserted into the guide sleeves 102a, for example the drill or high energy source for forming the initial through hole, so use of the tool etc. is more convenient to the surgical personnel performing the procedure.

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After the arcuate through aperture 6a is formed, then the implant 160 is inserted therein so it is disposed within the through aperture 6a in one vertebrae 2, passes or extends across the intervertebral space 4 and disposed within the through aperture 6a of the other vertebrae. The implant 160 is made from any one or more suitable materials such as e.g. a metal such as titanium or stainless steel, bone, bone with bone morphogenic protein, carbon fiber composite, nitinol. The implant being inserted into the final aperture is made from one or more of a metal (e.g., titanium or stainless steel), bone, morphogenic protein (including a combination of bone and bone morphogenic protein), carbon fiber composite, nitinol or biodegradable materials such

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as polyactic acid or polyglycolic acids and copolymers and other derivatives thereof, or collagen and collagen coated metal or bone. The implant also may comprise an in situ-formed plug where the aperture acts as a mold for an epoxy or other polymer-based system. The implant, preferably is curved so it generally conforms to the radius of the arcuate through apertures 6a in each vertebrae 2, however, other geometric shapes are contemplated that are consistent with the intended use including straight members.

The implant 160 suitably can be provided with a circular or oval shape. The diameter or width of the implant can vary over a relatively broad range and may depend on the size of the vertebrae and desired implant stiffness. More specifically, in preferred embodiments, the implant may suitably range in diameter or width from about 5 mm or as small as is mechanically sufficient, to sizes approaching that of large intramedullar rods, or about 22 mm. Preferably the implant should have a diameter or width from about 7 to 12 mm, more preferably about 9 mm. The implant also preferably should have an appropriate radius of curvature such that both vertebrae are engaged while staying well clear of the spinal cord. That radius preferably is about 1.5 inches, as referenced from the arcuate implant's inner radius.

The implant 160 is suitably a solid or hollow (e.g., tubular) member. The implant can be suitably configured so as to have fenestrations 166 (FIG. 6A) that allow biologic elements of bone to traverse through it or across it, thereby enhancing potential for stability and for cross-segmental healing. In particular, the implant 160 can have cutting fenestrations similar to a cheese grater, allowing fragments of bone to be pared off as the implant 160 is being inserted into the through apertures in either vertebrae. A fenestrated implant 160 that is hollow can be filled with bone chips or synthetic or engineered bone healing materials, allowing for bone ingrowth, and a cheese grater type of implant with cutting fenestrations can add freshly pared fragments of bone to the packed bone chips or other materials to enhance bony ingrowth. Additionally, the fenestrations 166 can be surface dimples, sharpened edges, cutting indentations or other alterations in the exterior surface of the implant

160 to enhance or further ensure the secure fitting of the implant into the arcuate through aperture 6a as well as for facilitating bone growth.

The particular technique for inserting the implant 170 into the through aperture 5 6a of a vertebrae 2 for fixing of the movable segment is dependent upon the material used to make the implant. For an implant 160 made from titanium, and as shown in FIG. 5A, a threaded end 162 (e.g., a female threaded end) is provided at one end of the titanium implant 160 for threaded engagement with the threaded counterpart (e.g., 10 male counterpart) at one end 172, the distal end of the guide wire 170. This can be accomplished for example by removing at least one of the guide sleeves 102 from the entrance opening of one through aperture 6a so the threaded end 172 of the guide wire 15 is exposed. The implant threaded end 162 is then screwed onto the guide wire threaded end 172 and the so tethered end 162 of the implant 160 is positioned at the entrance opening of the through aperture 6a and pulled into place by pulling on, for example, the proximal end 174 of the guide wire 170.

Preferably, the distal end 108 of one guide sleeve 102 remains engaged at the entrance opening for the other through aperture 6a, so as to serve as a bearing surface or brace for the guide wire 170 as it is being pulled out of this entrance opening. This 20 is done to keep the guide wire 170 from cutting through the cancellous bone when the guide wire is under tension because of the pulling action. Alternatively, a tubular member with a rounded surface may be advanced over the guide wire and through the remaining guide sleeve 102, to ensure that the guide wire pulls from the appropriate angle. This technique is suitable for use with metallic and other rigid material type of 25 implants.

Alternatively, and as shown in FIG. 5B, a pushing mechanism is useable for inserting or tamping the implant 160 into the arcuate through apertures 6a. In the illustrated embodiment, an arcuate pushing mechanism 300 is configured so as to 30 rotate about an axis of rotation that corresponds generally to the center of the circle subscribed by the arcuate through apertures 6a. The arcuate pushing mechanism

applies a force to the distal end of the implant 160 so as to drive the proximal end of the implant through the arcuate through aperture 6a in one vertebrae, across the intervertebral space 4 and into the arcuate through aperture 6a of the other vertebrae 2.

5 In the illustrated embodiment, the positioning jig 100 is removed except for the intervertebral spacing member 110 or bone intervertebral spacer where the intervertebral spacer 114 remains disposed in the intervertebral space 4. The arcuate pushing mechanism 300 is attached to the end of the interconnecting member 112 by means of a jig or other member or device so the pushing mechanism can rotate about
10 the end of the interconnecting member. In this way, the arcuate arm 302 of the pushing mechanism 300 can be advanced by having one of the surgical personnel rotating it about its axis of rotation. Alternatively, or in addition, the surgical personnel can strike one end 304 of the arm 302 with a mallet or other weighted object so as to drive the implant 160 into the through aperture 6a. For example,
15 striking may be required near the end of the insertion process when there is maximum friction being developed on the inserted implant. The arm 302 also may be configured with a curved support sleeve 306 in which the implant is received.

 Although the implant 160 and through apertures 6a are sized so that there is
20 preferably at least a snug-fit therebetween, as an extra measure of protection, the implant 160 may be further secured in place at its ends by means of screws 400 as shown in FIG. 6C. Alternatively, the implant 160 may be secured in place by a plate, screw, staple or a combination thereof. Additionally, the implant can be arranged so as to include a biting or expansion element(s) that can be driven out in a lateral
25 direction so as to engage the bony structure of the vertebrae 2.

 As provided above, and as shown in FIGS. 7A-B, the implant 160a can be made from nitinol. A nitinol implant 160a is advantageous in that a curved nitinol implant can be straightened as shown in FIG. 7B prior to insertion into the arcuate
30 through apertures 6a. The straightened nitinol implant 160a can be advanced down one of the guide sleeves 102 in any of a number of ways, for example, by pushing or

pulling, so it can be driven into the arcuate through apertures 6a. The nitinol implant 160a also can be inserted into the arcuate through apertures 6a in any of the other fashions described above in connection with FIGS. 5A-B.

5 Additionally, a sharp edge of the nitinol implant can be used like a reamer or awl to thereby enlarge the initial through hole 6 as the implant is being inserted or driven into the initial though aperture. This avoids the intermediate step of drilling or otherwise forming the arcuate through aperture 6a before insertion of the implant.

10 FIG. 7C depicts an illustrative device 400 for inserting a nitinol implant 160a, which device includes a guide tube 402 and a pusher 404. The distal end 408 of the guide tube 402, similar to the positioning jig guide sleeve distal end 108 is preferably configured so as to be capable of releasably mating with a surface, or portion thereof, of the vertebrae 2 where the entrance of the arcuate through aperture 6a is located. In
15 the illustrated embodiment, the guide tube distal end 408 is configured with a cut out so as to receive a corner of the vertebrae 2 therein.

The distal end 408 is disposed on the vertebrae so that the lumen therein is aligned with the arcuate through aperture 6a. The straightened nitinol implant 160a is
20 inserted into the guide tube 402 along with the pusher 404 such that the distal end of the pusher is in contact with the proximal end of the nitinol implant. The pusher distal end 408 mates with the implant proximal end so as to maintain the orientation and direction of the nitinol implant 160a within the guide tube 402 so that it curves in the proper direction when it exits the guide tube. Alternatively, and as shown in FIGS.
25 8A-B, the orientation of the nitinol implant 160a within the guide tube 402 is maintained with a flat side or with a key and notch type of arrangement.

The pusher 404 includes a stop 406 to limit the travel of the pusher within the guide tube 402. This in turn limits the amount of travel by the nitinol implant 160a so
30 as to assure that the implant remains buried within the vertebrae and not exposed above the surface thereof.

The placement of the implant according to the systems and methods of the present invention is advantageous in that the inserted implant resides completely within the vertebrae and, thus, within the spine, with no protrusion as compared with prior art devices. The implant and its placement provide a configuration which allows for some compression and cantilever force, but deters rotation and shear. Additionally, in the present device, the moment arm is more centrally located within the spine as compared to prior devices. This central location also provides better stability in the face of torsion as compared to prior art devices.

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In general, the placement of an arcuate implant within the arcuate through apertures as described herein is particularly advantageous because the implant is buried to avoid contact with neurovascular structures. The placement provides load sharing and thus provides a better healing bio-mechanical environment and also provides a more advantageous fixation to avoid mechanically sub-optimal stresses. Also important, this method allows securement and avoids displacement of a spinal fusion or disk replacement device without modification or damage to the vertebrae's load bearing surface. Rather, one or two holes placed in or around the center of a vertebrae can be sufficient. The method and positioning jig 100 of the present invention also are advantageous in that the jig can be adapted for use in minimally invasive procedures. Additionally, the capability to position implants in accordance with the methods described herein enables avoiding blood vessel injury, erosion into organs and damage to adjacent nerves. This provides a significant advantage over presently existing technologies for disorders of the spine including fractures, arthritis, deformity, infections, tumor and mechanical spinal disorders.

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Although the foregoing method describes extending a single implant between adjacent vertebrae this description should not be construed as being a limitation as one or more implants can be positioned across each motion segment as described herein.

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In addition, the above described method can be further adapted so as to be used to secure an intravertebral prosthetic device 500 (i.e., artificial disc) such as that shown in FIG. 6A. According to this aspect of the invention, the implant is made partly or wholly from a flexible material such as silicon, elastomeric polymers, polyurethanes and copolymers thereof, hydrogels, collagen, bioabsorbables, compositions, or a metallic spring or coil, so as to allow continual mobility between the vertebral bodies. One or more arcuate implants are provided which pass through a partial or complete hole in the prosthesis. This effectively prevents the prosthesis from becoming dislodged as well as maintaining its location and orientation within the disc space.

There is shown in FIGS. 17A-C exemplary arcuate implants 160b-d for use in securing the intravertebral prosthetic device 500 within the bones of the spine. Referring now to FIG. 17A, there is shown an arcuate implant 160b having a first section 163 disposed between two end or second sections 165 that mechanically engage the first section. The first section 163 is made up of a compressible material and the second sections 165 are made up of a material(s), such as metals and bone, that is conducive to the attachment of the second sections to the bone thereby securing the implant 160b. Alternatively, and as shown in FIG. 17B, the implant 160c can comprise a first section 163 that is bonded or otherwise mechanically secured to the second sections 165.

The implants 160b,c of either FIGS. 17A,B extends through an aperture or hole in the prosthetic device 500 and into the vertebral bodies adjacent to the prosthetic device similarly to that illustrated in FIG. 16A. Additionally, the first section 163 of either of the two implants 160b,c is arranged so as to extend through the prosthetic device 500. See also the discussion above for FIG. 16A for other aspects of securing the prosthetic device (e.g., one or more apertures in the prosthetic) and materials for the implant.

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The above described method also can be further adapted so as to be used to secure an intravertebral prosthetic device 500 (i.e., artificial disc) according to another technique such as that shown in FIG. 6B using an implant, such as the exemplary implant 160d shown in FIG. 17C. In this technique any of the mechanisms and methods described herein are used to form at least an aperture 6, preferably an arcuate through aperture, in one adjacent vertebral body 2a. More particularly, the aperture forming mechanism or method also forms another aperture 6' in the other adjacent vertebral body 2b. This another aperture 6' in the other vertebral body 2b is not a through aperture but rather only extends only into a portion of the other vertebral body. After forming the apertures 6,6', the prosthetic device 500 is disposed in the disc space or intervertebral space 4. The implant 160d is then pressed into and through the aperture 6, through the prosthetic device 500 and intervertebral space 4 and into the aperture 6' of the other adjacent vertebral body 2b.

The exemplary arcuate implant 160d shown in FIG. 17C includes a first section 163 and a single second section 165 that mechanically engages the first section as shown in FIG. 17A or is bonded or other wise mechanically secured to the first section as shown in FIG. 17B. Reference shall be made to the above discussion regarding FIGS. 17A,B for further details regarding the make up and materials of the first and second sections 163, 165 and the discussion for FIG. 16A for other aspects of securing the prosthetic device (e.g., one or more apertures in the prosthetic) and materials for the implant.

FIG. 9 shows a method for inserting an implant 600 according to a second aspect of the present invention. A final through aperture 604 is formed in each of the vertebrae in accordance with above described techniques such as by drilling. Except that the through aperture 604 that receives the implant can be straight as shown in FIG. 9 or can be arcuate as shown in any of FIGS. 3-6. As such, reference should be made to the foregoing discussion for further details regarding the formation of the final through aperture 604.

In the method according to the second aspect, the implant is in two sections 602a,b. The proximal ends 608 of the two sections 602a,b are particularly configured so they can be mated to each other and interlocked to each other by means of an interference fit, a nut and bolt, a screw or a pin 606. Thus, to fix the moveable
5 segment, one section 602a is inserted into the through aperture 604 in one vertebrae 2 and the second section 602b is inserted into the through aperture 604 of the other vertebrae. The two sections 602a,b are inserted into their respective through apertures until the proximal ends 608 thereof are mated to each other. The pin 606 or other
10 securing mechanism is then used to interlock the proximal ends and thus form a rigid implant. Although the sections are illustrated as being straight, it is within the scope of the present invention for the sections to arcuate so as to form an interlocking rod when assembled.

FIG. 10 shows a method for inserting an implant 600 according to a third
15 aspect of the present invention. According to this method, the apertures 702 in each vertebrae 2 are formed so they extend from the vertebral space 4 outwards, penetrating into the cancellous bone. In this aspect, the apertures 704 formed in the vertebrae need not be through apertures. The implant 600 is like that described above for the second aspect of the present invention except that it is inverted from that shown in
20 FIG. 9.

There is respectively shown in FIGS. 11A,B a cutter bracket system 1100 and a curved bit or drill system 1120, the curved drill system being for use with such a cutter bracket system. The cutter bracket system 1100 and curved drill system 1120
25 comprises another embodiment of the present invention for forming arcuate apertures 6a (FIG. 6A) in each of the adjacent vertebral bodies 2. Referring now to FIG. 11A, the cutter bracket system includes temporary vertebral screws 1102, pivot brackets 1104 and a pivot arm 1106. In the illustrated embodiment, there is two temporary vertebral screws 1102 that are each secured to the adjacent vertebral body 2 that is to
30 be fused, however, this shall not be construed as a limitation on the number of intervertebral screws. Extending from the temporary vertebral screws 1102 are the

pivot brackets 1104, which locate the pivot point 1108 with respect to the adjacent vertebral bodies 2 and maintain the pivot point in this orientation. The pivot arm 1106 is rotatably mounted to the pivot brackets 1104 using any of a number of mechanisms or techniques known in the art so that the pivot arm pivots or rotates about the pivot point 1108. In an exemplary embodiment, the temporary vertebral screws 1102, the pivot brackets 1104 and the pivot arm 1106 are made from stainless steel although other materials are contemplated.

The drill system illustrated in FIG. 11B includes a curved cannula 1122, a flexible cable 1124, a cutting head or burr 1126 and a motor 1130. The flexible cable 1124 is rotatably disposed with the curved cannula 1122. One end of the flexible cable 1124 is attached to the cutting burr 1126 and the other end of the flexible cable 1124 is attached to the motor 1130, whereby the motor drives the cutting burr so it rotates in the desired manner. In the illustrated embodiment, the motor 1130 also is mounted to an end of the curved cannula 1122. In an exemplary embodiment, the curved cannula 1122 is made from stainless steel and the flexible cable 1124 is a flexible, teflon coated stainless steel cable, the cutting burr 1126 is made from stainless steel, although it is within the scope of the present invention for other materials to be used.

The motor 1130 includes any of a number of devices known in the art that develop or provide a rotary output which can be used to rotate the flexible cable 1124, such devices include, but are not limited to, electric or pneumatic drills, DC/AC electric motors, or , pneumatic, air driven rotary motors. It also is within the scope of the present invention for the drill system 1120 to further include a coupling member, as is known in the art, that operably and rotatably interconnects the flexible cable 1124 and the motor 1130 such that the motor is located remote from the curved cannula 1122. In this way, any of a number of rotary devices such as a drill, that are readily available, can be adapted for use in the drill system 1120 of the present invention and interconnected to the flexible cable 1124 by means of the coupling member.

The drill system 1120 is mounted or attached to the pivot arm 1106, distal from the pivot point 1108, by means of a connector 1128 on the curved cannula 1122. The connector 1128 and the corresponding feature on the pivot arm 1106 comprises
5 any of a number of mechanisms or devices known in the art (e.g., clamp type mechanism) by which the curved cannula can be removably secured to the pivot arm so there is essentially no relative movement therebetween. In a particular embodiment, the curved cannula 1122 is secured proximal to or at the distal end of the pivot arm. In this way when the drill system 1120 is secured to the cutter bracket
10 pivot arm 1106 and the cutter bracket pivot arm 1106 is rotated about the pivot point 1108, the pivot arm guides the curved drill system, in particular the cutting burr 1126 on a well-defined circular path.

In use, the cutter bracket system 1110 is temporarily secured to the adjacent
15 vertebral bodies 2 to be fused by the temporary vertebral screws 1102. In particular, the cutter bracket system 1110 is secured to the vertebral bodies 2 so that the pivot point 1108 is positioned so as to be spaced from a surface of the vertebral bodies and so as to be between the adjacent vertebral bodies, more particularly at about the midpoint of the intervertebral space 4. After securing the cutter bracket system to the
20 vertebral bodies the curved drill system 1120 is mounted to the pivot arm as described above.

The pivot arm 1106 is then rotated in one direction, for example a clockwise direction, about the pivot point 1108. As the pivot arm 1106 is rotated thereabout,
25 the cutting burr 1126 is operated so the drill system 1120 drills an arcuate hole in the vertebral body 2 on one side of the pivot point. The curved drill is then remounted so the cutting burr 1126 is on the other side of the pivot point 1108 and the pivot arm is rotated in a counter clockwise direction so the drill system 1120 drills an arcuate hole in the vertebral body 2 on the other side of the pivot point 1108. In an exemplary
30 embodiment, the arcuate hole is completely formed when the pivot arm 1106 bottoms out or contacts the vertebrae being drilled. After forming the arcuate holes, the curved

drill system 1120 is dismantled from the pivot arm 1106 and the cutter bracket system 110 is disconnected from the adjacent vertebral bodies 2. In this way, two matched arcuate holes are formed in the adjacent vertebral bodies 2 that are sized and configured to receive an arcuate implant being inserted therein. Reference shall be made to the foregoing discussion for further details regarding such an arcuate implant or fixation member.

Although the foregoing describes the formation of the arcuate holes or apertures 6a in the adjacent vertebral bodies 2 using a curved drill system 1120 mounted to the pivot arm 1106, this shall not be construed as a limitation. As discussed hereinabove, it is within the scope of the present invention for other devices, mechanism or techniques, such as the above-described ablation energy sources, to be adapted for use with a rotating pivot arm 1106 to form the through holes/ apertures. As such these other devices, mechanisms or techniques are contemplated for use with the above-described cutter bracket system.

In accordance to another method of the present invention, a slot is cut in each of the adjacent vertebral bodies and a biscuit implant is inserted into the slots so as to also bridge across the intervertebral space 4. Preferably the slots are simultaneously cut in the vertebral bodies so a common channel is formed therein. In an exemplary embodiment, and with reference to FIGS. 12A,B there is provided a cutting device 1200 having a cutting implement, for example a circular blade 1206 that is rotated by a motor (not shown). The cutting device 1200 also is configured so the blade 1206 is moveable between a first position, where the blade is disposed within the device housing 1202 (FIG. 12A), and a second position, where a portion of the blade extends outwardly a predetermined distance from an exterior side 1204 of the housing (FIG. 12B). Preferably, the exterior side 1204 from which the blade 1206 extends is configurable so that in one position the exterior side is substantially parallel to a tangent at the midpoint of the blade and further includes indicia 1208 representative of the mid-point of the blade.

In use, and as shown in FIG. 12C, the cutting device 1200 is positioned so the device housing exterior side 1204 abuts or is adjacent to the vertebral bodies 2 and so the indicia 1208 representative of the blade midpoint is pointing towards the intervertebral space 4, preferably about a midpoint between the adjacent vertebral
5 bodies. The rotating circular blade 1206 is then moved from the first to the second position so as to simultaneously cut an arcuate slot in each of the adjacent vertebral bodies 2. After cutting the slot, the circular blade 1206 is returned to the first position with the device housing 1202 and the cutting device 1200 is removed from the vertebral bodies.

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As shown in FIG. 12D, after the arcuate slot 1209 is cut in the adjacent vertebral bodies 2, a biscuit implant 1210a such as that shown in FIG. 12F, is inserted into the arcuate slot in each of the adjacent vertebral bodies and so as to bridge therebetween. The biscuit implant 120a is secured in the arcuate slot 1209 using any
15 of the methods described herein for the other implants of the present invention thereby fusing and stabilizing the adjacent vertebral bodies. Alternatively, a biscuit implant 1210b such as that shown in FIG. 12G, is configured so as to include a spacer element 1212. Thus, when the biscuit implant 1210b is inserted into the arcuate slots 1209 the spacer element 1209 thereof is received and disposed in the intervertebral space 4 as
20 shown in FIG. 12E.

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In addition to the exemplary biscuits implants 1210a,b illustrated in FIGS. 12F-G, it is within the scope of the present invention for the biscuit implant, whether it is configured with or without a spacer element 1212, to be formed in any of a
25 number of geometric shapes that are otherwise consistent with the intended use. This includes the biscuit implants 1210c-f shown in FIGS. 12H-K. Reference shall be made to the foregoing discussion regarding the other implants or fixation members of the present invention as to the materials and other features (e.g., fenestrations) which apply equally for a biscuit implant according to the present invention.

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There is shown in FIGS. 13A-13F, an implant system according to these systems and methods. FIG. 13A shows an embodiment of the inner implant 800 adapted for inspection within the outer implant 810 shown in FIG. 13B. The inner implant 800 in FIG. 13A is shown as a substantially hollow device equipped with a fenestrated wall 802. The inner implant 800 bears on a lateral surface 814 a key slot 804 adapted to secure and orient the inner implant 800 within the outer implant 810 shown in FIG. 13B. Specifically, the key slot 804 in the illustrated embodiment can slide into a key groove 808 situated on the inner aspect 818 of the outer implant 810. In the embodiment shown in FIG. 5B, the outer implant is equipped with a trough and trough slit and a fenestrated wall 812 as shown in FIG. 13D. It is understood that the devices shown in these figures can be fabricated from a plurality of materials including both absorbable and non-absorbable biocompatible materials. Materials may include metallics, ceramics, plastics, polymers, biological materials and materials produced by biotechnology. A variety of suitable materials will be readily envisioned by those of ordinary skill in the art for use in the system and methods of the present invention.

FIG. 13C shows a lateral view of two vertebral bodies 820 and 822 showing the general position of the implant system 824. In more detail, the edge of the outer implant 828 is shown imbedded and buried in the vertebral bodies 820 and 822. The edge of the inner implant 830 is shown positioned within the intervertebral disc space 834. A set of bone cuts 832 and 836 are made at the buried end of the implant system 824. FIG. 13D shows an anterior view of the outer implant 838 positioned with the inner implant 840 secured within it according to the systems and methods of the present invention. FIG. 13E shows an anterior view of the inner implant 844 secured within the outer implant 842 according to the systems and methods of the present invention. In FIG. 13E, however, the entire implant system 845 is shown in the rotated 90 degrees relative to the angle at which the implant system 848 is inserted into the vertebral bodies and disc space (not shown). The inner implant 844 in this view assumes a vertical position within the implant system 848, and the outer implant is rotated 90 degrees to effect this repositioning.

FIG. 13F shows in more detail a perspective view of an embodiment of the implant system 850 according to the present invention. The inner implant 854 is shown positioned within the outer implant 858, the entire implant system 850 being turned vertically. As a consequence of this repositioning, two bone sections 860 contained between the inner implant 854 and the outer implant 858 are turned to a vertical position. These bone sections 860 thus provide structural stability to the system 850 and to a spine unit (not shown). The vertical repositioning places cortical bone in a more supportive position.

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In the illustrated embodiment, the outer implant 858 is shown with a fenestrated wall 852 for facilitating bony ingrowth. These fenestrations are larger at the upper and lower confines of the repositioned bone graft sites to enhance fusion. Also in the illustrated embodiment, the inner implant 854 is shown with a hollow interior section 862 available for containing a solid displacing shim and bone chips, bone matrices, growth factors or other agents for encouraging or facilitating bony ingrowth and enhancing stable positioning of the verticalized cortical bone sections. Other substances useful to the healing process can be provided within this interior section 862. For example, antibiotics can be placed in this interior section 862 in a suitable vehicle. Other substances and matrices can be envisioned by practitioners of those arts that will fall within the scope of the present invention.

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In more specific embodiments, the outer implant 838,858 is configured so as to include an axially extending slot or slit 841,864 that is arranged and configured so as to permit adjustment of the diameter of the outer implant, for example to permit the outer implant to be expanded outwardly. Thus, bone sections can be placed with as tight a positioning as possible and the outer implant 838,858 can be placed in firmer or closer engagement with the vertebral bodies 820,822. The structure forming the adjustment slit 841,864 includes any of a number of configurations, structures or arrangements that permit relative movement between the sides of the outer implant on either side of the adjustment slit. Such structures, arrangements and configurations

include, but are not limited to an axially extending through aperture or an axially extending ship-lap type of joint where portions of the axially extending sides slidably overlap each other.

5 There is generally shown in FIGS. 14A - 14C, an inner tool 900 to be used according to the systems and methods of the present invention. FIG. 14A shows the inner tool 900 positioned with the intervertebral disc space 906. The inner tool 900 bears on its distal end, a shorter disc end 902 that is adapted for insertion within the intervertebral disc space 906 to allow for cutting a segment of the vertebral bodies 904
10 and 908 above and below it. FIG. 14B shows a perspective view of an inner tool 910 according to the systems and methods of the present invention. The distal end 912 thereof is adapted for cutting the cortical vertebral end plates that it abuts. FIG. 14C shows in more detail an embodiment of the cutting mechanism bone by the inner tool 916. A cutting end 914 at the distal end of the tool 916 bears a set of stop cut blades
15 shown here in the retracted position 920 and in the extended position 918. Directing the blades from the retracted position 920 to the extended position 918 effects a cut in the adjacent bone (vertebral endplate, not shown). While the depicted embodiment of a tool can be advantageously employed in conjunction with the implant system according to these systems and methods other tools and devices can be envisioned by
20 skilled practitioners of these arts for cutting bone and for positioning an implant system all modification that fall within the scope of the present invention.

Figure 15 shows a lateral view of an embodiment of the tool system 1000 according to the present invention positioned in relation to the vertebral bodies 1014
25 and 1018. In this view an inner tool 1002 is shown with its distal end positioned between the vertebral bodies 1014 and 1018. An outer tool 1004 is shown in two positions, a position 1008 before driving it into the vertebral bodies 1014 and 1018 and a position 1020 after driving it into the vertebral bodies 1014 and 1018. A blade 1022 of the outer tool 1004 is shown positioned at the anterior aspect of the vertebral
30 body 1014 before the outer tool 1004 is driven into the vertebral body 1014. In this position 1020 after driving the tool 1004 into the vertebral body 1018, the blade 1024

is shown imbedded in the vertebral body 1018, having cut it perpendicular to its anterior face. The inner tool 1002 can make bone cuts 1012 at right angles to the blade 1024 of the outer tool 1004, thereby creating a bone slab 1010 that can be repositioned according to the systems and methods of the present invention. This
5 bone slab 1010 (section) can be cut so as to allow for anterior vertebral distraction by making these slabs oblong rather than circular.

It should be clear that the methods, systems, and devices of the invention are not limited to securing a pair of vertebrae, but rather any combination of multiple
10 vertebrae segments. It also should be clear that the methods, systems, and devices are in no way limited to vertebrae segments. In particular, the invention enables securing any solid substrates, particularly bone substrates, without use of protruding screws or plates. In this regard, FIG. 16 shows a bone-to-bone application using techniques of the invention. It also should be understood that the invention is applicable to a wide
15 variety of fixation configurations, including bone-to-bone with a gap; bone-to-bone without a gap; bone-to-bone with bony spacers; and bone-to-bone with a non-bony spacer such as a metal, polymer, or a biodegradable material.

Although a preferred embodiment of the invention has been described using
20 specific terms, such description is for illustrative purposes only, and it is to be understood that changes and variations may be made without departing from the spirit or scope of the following claims.

What is claimed is:

1. A method for stabilizing adjacent vertebrae of a spine, comprising implanting an arcuate fixation member between the vertebrae.
2. The method of claim 1 wherein the member is implanted through a preformed aperture in each of the adjacent vertebrae.
3. The method of claim 1 wherein the preformed aperture has been drilled in each of the adjacent vertebrae.
4. The method of claim 1 wherein apparatus the fixation member is the sole apparatus employed to affix the vertebrae.
5. The method of claim 1 wherein the member is made from one or more of a metal, bone, morphogenic protein, carbon fiber composite, nitinol, a biodegradable material, collagen or collagen coated metal or bone.
6. The method of claim 1 wherein the implant is one of solid, hollow or with ingrowth fenestrations and screw holes or expansion bolts or staples.
7. A method for stabilizing adjacent vertebrae of a spine, comprising:
providing a positioning apparatus including two guide sleeves, each guide sleeve having a long axis;
locating the two guide sleeves with respect to the adjacent vertebrae such that a vertex formed by the long axis of each guide sleeve is located in the intervertebral space for the adjacent vertebrae;
forming an aperture in each of the adjacent vertebrae using the guide sleeves;
and

inserting an implant into the apertures formed in each of the adjacent vertebrae so that the implant extends between the adjacent vertebrae and through the intervertebral space.

8. The stabilizing method of claim 7 wherein said step of forming includes forming an arcuate aperture in each of the adjacent vertebrae such that the arcuate apertures in the adjacent vertebrae have a common axis of rotation.

9. The stabilizing method of claim 7 wherein the step of forming includes forming an aperture in each of the adjacent vertebrae by one of drilling or ablation of the bone by an energy source.

10. The stabilizing method of claim 8 wherein the step of forming includes forming an aperture in each of the adjacent vertebrae by one of drilling or ablation of the bone by an energy source.

11. The stabilizing method of claim 8 wherein the step of forming includes:
drilling an initial aperture in each of the adjacent vertebrae so as to create intersecting apertures with convergent paths within the intervertebral space; and
enlarging the initial aperture so as to form the aperture that receives the implant.

12. The stabilizing method of claim 11 wherein the step of enlarging includes enlarging the initial aperture using one of a drill bit, a reamer, an awl, coring device or energy source.

13. The stabilizing method of claim 11 wherein the method of forming further includes inserting a drill bit into each of the guide sleeves for drilling of the initial aperture.

14. The stabilizing method of claim 11 wherein the step of forming further includes;

inserting a guide member, after drilling of the initial aperture, into one of the guide sleeves, down through the initial aperture in one adjacent vertebrae, through the intervertebral space and into the initial aperture in the other adjacent vertebrae; and

advancing an aperture-enlarging device over the guide member to enlarge the initial aperture.

15. The stabilizing device of claim 14 wherein the aperture enlarging device is one of a curved reamer, curved drill bit or coring device, and wherein said step of advancing includes advancing the one of the curved reamer, the curved drill bit or coring device over the guide member so as to form an arcuate aperture in each of the adjacent vertebrae.

16. The stabilizing method of claim 7 wherein the step of forming includes:

inserting a drill bit into each guide sleeve;

drilling an initial aperture in each of the adjacent vertebrae so as to create intersecting apertures with convergent paths within the intervertebral space;

inserting a guide member, after drilling of the initial aperture, into one of the guide sleeves, down through the initial aperture in one adjacent vertebrae, through the intervertebral space and into the initial aperture in the other adjacent vertebrae; and

advancing an aperture-enlarging device over the guide member to enlarge the initial aperture to form the aperture that receives the implant.

17. The stabilizing method of claim 16 wherein the aperture-enlarging device is one of a drill bit, a reamer, an awl or energy source.

18. The stabilizing method of claim 16 wherein the aperture enlarging device is one of a curved reamer, a curved drill bit, a curved drill or an energy source, and wherein the step of advancing includes advancing the one of the curved reamer,

the curved drill bit, the curved drill or the energy source over the guide member so as to form an arcuate aperture in each of the adjacent vertebrae, the arcuate apertures in the adjacent vertebrae having a common axis of rotation.

19. The stabilizing method of claim 7 wherein the positioning apparatus being provided further includes a cross member and an intervertebral spacer, where the guide sleeves are pivotally mounted to the cross member and the intervertebral spacer is spaced from the cross member and interconnected thereto at about a mid point between the pivots points for the guide sleeves; and wherein said stabilizing method further comprises:

locating the intervertebral spacer in the intervertebral space between the adjacent vertebrae; and

maintaining alignment of the guide sleeves with respect to the adjacent vertebrae so that a consistent angle is maintained between the guide sleeve and the vertebrae during at least a portion of said forming of the aperture.

20. The stabilizing method of claim 11 wherein the positioning apparatus being provided further includes an intervertebral spacer; said stabilizing method further comprises the step of locating the intervertebral spacer in the intervertebral space between the adjacent vertebrae; and wherein the intervertebral spacer is configured so as to provide protection to the spine during said drilling when disposed in the intervertebral space.

21. The stabilizing method of claim 8 wherein the step of implanting includes successively drawing a portion of the implant through the arcuate aperture in one adjacent vertebrae, through the intervertebral space and into the arcuate aperture of the other adjacent vertebrae.

22. The stabilizing method of claim 8 wherein the step of implanting includes:
securing one end of a guide wire to an end of the implant;
passing a free end of the guide wire through the arcuate aperture in one of the adjacent vertebrae, through the intervertebral space and through the arcuate aperture in the other adjacent vertebrae; and
pulling on the guide wire free end to thereby successively draw the portion of the implant.

23. The stabilizing method of claim 8 wherein the step of implanting includes:
inserting a beginning end of the implant into an entrance opening of one of the adjacent vertebrae;
applying a force to the portion of the implant extending from the entrance opening so as to drive the implant beginning end through the arcuate aperture in the aperture of said one of the adjacent vertebrae, through the intervertebral space and into the arcuate aperture in the other of the adjacent vertebrae.

24. The stabilizing method of claim 8 wherein the method further comprises:
inserting a beginning end of the implant into an entrance opening of one of the adjacent vertebrae; and
applying a force generated by a force generating mechanism to the portion of the implant extending from the entrance so as to drive the implant beginning end through the arcuate aperture in the aperture of said one of the adjacent vertebrae, through the intervertebral space and into the arcuate aperture in the other of the adjacent vertebrae.

25. The stabilizing method of claim 24 wherein the method further comprises:

locating an intervertebral spacer in the intervertebral space between the adjacent vertebrae; and

attaching the force generating mechanism to the intervertebral spacer.

26. The stabilizing method of claim 7 wherein the implant is made from one or more of a metal, bone, morphogenic protein, carbon fiber composite, nitinol or a biodegradable material.

27. The stabilizing method of claim 7 wherein the implant is one of solid, hollow or with ingrowth fenestrations.

28. The stabilizing method of claim 7 wherein one end of each guide sleeve, the end which contacts a surface of the adjacent vertebrae is configured to accept a surface feature of the adjacent vertebrae surface and includes surface artifacts that mechanically engage the adjacent vertebrae.

29. The stabilizing method of claim 7 wherein the implant includes a first and a second section and a distal end of each of the first and second sections being configured so as to be capable of being secured together; and wherein the method further comprises:

inserting the implant first section into the aperture in one of the adjacent vertebrae so that the distal end therefore is disposed in the intervertebral space;

inserting the implant second section into the aperture in one of the adjacent vertebrae so that the distal end therefore is disposed in the intervertebral space;

securing the distal ends of the first and second sections together.

30. The stabilizing method of claim 29 wherein the apertures in the adjacent vertebrae are arcuate and wherein the implant first and second sections are arcuate having a radius substantially the same as that for the arcuate apertures.

31. The stabilizing method of claim 29 wherein a long axis for each of the first and second sections is substantially straight.

32. The stabilizing method of claim 7 further comprising the step of securing a portion of the implant proximal the ends thereof to the adjacent vertebrae.

33. The stabilizing method of claim 29 wherein the step of securing the distal ends includes securing the distal ends by one of a nut, bolt, pin, staple, or expansion bolt.

34. An implantable spinal fixation system, comprising:
an arcuate implant member of a size sufficient to extend between two adjacent vertebrae.

35. The system of claim 34 wherein the implant member is constructed of one or more of a metal, bone, morphogenic protein, carbon fiber composite, nitinol or a biodegradable material.

36. A spinal system comprising:
a mammalian spine with a surgically implanted arcuate member extending between two adjacent vertebrae.

37. The system of claim 36 wherein the arcuate member is constructed of one or more of a metal, bone, morphogenic protein, carbon fiber composite, nitinol or a biodegradable material.

38. A spinal fusion kit comprising an arcuate fixation member.

39. A spinal fixation kit comprising a positioning apparatus including:
two guide sleeves, each guide sleeve having a long axis,
a cross member,
an intravertebral spacer;
wherein the guide sleeves are pivotably mounted to the cross member, and
wherein the intravertebral spacer is spaced from the cross member and
interconnected thereto so as to be between the pivots points for the guide
sleeves; and
a fixation member.
40. The spinal fixation kit of 39, wherein the fixation member is arcuate.
41. The spinal fixation kit of claim 40, wherein the fixation member is one
of a solid or hollow member.
42. The spinal fixation kit of claim 40, wherein the fixation member is
configured with at least one fenestration.
43. The spinal fixation kit of claim 39, wherein:
the fixation member includes a first section and a second section, a distal end
of each of the first and second sections being configured so as to be capable of being
secured together thereat; and
a mechanism that secures the distal ends of the first and second sections
together.
44. The spinal fixation kit of claim 39, further comprising a guide wire, an
end of the guide wire being configured to be interconnected to one end of the fixation
member, and the guide wire being used to implant the fixation member in adjacent
vertebrae.

45. The spinal fixation kit of claim 39, wherein the fixation member is made from one of a metal, bone, bone with bone morphogenic protein, carbon fiber composite, nitinol or a biodegradable material.

46. The spinal fixation kit of claim 39, further comprising a force generating device used to apply a force to the fixation member for implanting the fixation member in adjacent vertebrae.

47. A method for fixing two adjacent vertebrae to facilitate a bony union thereof, comprising:

performing a discectomy of an intervertebral space;

transecting a segment of bone from a surface of a vertebra bordering the intervertebral space;

freeing the segment of bone from the surface of the vertebra from a horizontal to a vertical plane;

securing the segment of bone in the vertical plane to span the intervertebral space, thereby fixing two adjacent vertebrae to facilitate a bony union thereof.

48. A method for stabilizing adjacent vertebrae of a spine, comprising:

providing a positioning apparatus including a pivot arm that is rotatable about a pivot point;

locating the positioning apparatus with respect to the adjacent vertebrae such that the pivot point is disposed between the adjacent vertebrae;

forming an aperture in each of the adjacent vertebrae responsive to rotation of the pivot arm about the pivot point; and

inserting an implant into the apertures formed in each of the adjacent vertebrae so that the implant extends between the adjacent vertebrae and through the intervertebral space.

49. The stabilizing method of claim 48 wherein said step of forming includes forming an arcuate aperture in each of the adjacent vertebrae.

50. The stabilizing method of claim 48 wherein the step of forming includes forming an aperture in each of the adjacent vertebrae by one of drilling or ablation of the bone by an energy source.

51. The stabilizing method of claim 48 wherein the step of locating includes locating the pivot point such that it is spaced from a surface of the adjacent vertebrae and disposed at a midpoint between the adjacent vertebrae.

52. The stabilizing method of claim 48 wherein the apparatus being provided further includes a drill that is affixed to the pivot arm such that when the pivot arm rotates about the pivot point the drill follows a defined arcuate cutting path.

53. The stabilizing method of claim 52 wherein the drill includes a curved drilling element.

54. The stabilizing method of claim 48 wherein the positioning apparatus further includes a frame to which the pivot arm is rotatably mounted and wherein the step of positioning includes securing the frame to the adjacent vertebrae so the pivot point is located at the desired position.

55. The stabilizing method of claim 51 wherein the pivot point is located opposite the intervetebral space.

56. The stabilizing method of claim 53 wherein the curved drilling element comprises a curved cannula, a flexible member disposed within the curved cannula, and a cutting burr affixed to an end of the flexible member, the flexible burr for cutting an arcuate aperture in each of the adjacent vertebrae.

57. The stabilizing method of claim 52 wherein the step of forming includes rotating the pivot arm in one direction to form the aperture in one of the adjacent vertebrae and rotating the pivot arm in an opposite direction so as to form the aperture in the other of the adjacent vertebrae.

58. The stabilizing method of claim 57 wherein the apparatus being provided further includes a drill that is affixed to the pivot arm such that when the pivot arm rotates about the pivot point the drill follows a defined arcuate cutting path, and wherein said step of forming further includes remounting the drill on the pivot arm prior to said rotating the pivot arm in the opposite direction so that the drill is positioned for forming the aperture in said other of the adjacent vertebrae.

59. The stabilizing method of claim 57 wherein the drill is a curved drill.

60. A method for stabilizing adjacent vertebrae of a spine, comprising:
providing a cutting device including a cutting implement having midpoint;
positioning the cutting device proximal a surface of the adjacent vertebrae and so that the cutting implement midpoint is located between the adjacent vertebrae;
cutting a common channel in the adjacent vertebrae with the cutting implement; and

inserting a biscuit implant into the common channel so that the implant extends between the adjacent vertebrae and through the intervertebral space, the space between the adjacent vertebrae.

61. The stabilizing method of claim 60 wherein the cutting device being provided is configured such that the cutting implement is moveable between a first position in which the cutting implement is disposed within the cutting device and a second position in which a portion of the cutting implement extends outside of the cutting device and wherein the step of cutting includes moving the cutting implement to the second position to cut the common channel in the adjacent vertebrae.

62. The stabilizing method of claim 60 wherein the biscuit implant includes a spacer element and wherein the step of inserting includes inserting the biscuit implant into the common channel such that the spacer element is disposed in the intervertebral space.

63. The stabilizing method of claim 60 wherein the step of positioning includes positioning the cutting device so the cutting implement midpoint is located at the midpoint between the adjacent vertebrae

64. A spinal fixation kit comprising a cutter bracket sub-system and a fixation member, wherein the cutter bracket sub-system includes:

a frame being configured so as to be removably securable to adjacent vertebrae, and

a pivot arm rotatably mounted to the frame.

65. The spinal fixation kit of claim 64 further comprising one of a drill or an ablation energy source.

66. The spinal fixation kit of claim 64 further includes a drill and wherein the pivot arm and the drill are configured so the drill is removably secured to the pivot arm.

67. The spinal fixation kit of claim 66 wherein the drill includes a curved drilling element.

68. The spinal fixation kit of claim 67 wherein the curved drilling element includes a curved cannula, a flexible member disposed within the curved cannula, and a cutting burr affixed to an end of the flexible member, the flexible burr being configured for cutting an arcuate aperture in a vertebrae.

69. A spinal fixation kit comprising a cutting device and a fixation member, wherein the cutting device includes a cutting element that is moveable from a first position in which the cutting element is disposed within a housing of the device and a second position in which a portion of the cutting element is disposed outside of the device housing.

70. The spinal fixation kit of claim 69 wherein the cutting element is a circular blade.

71. The spinal fixation kit of claim 70 wherein the fixation member is a biscuit implant configured to complement the shape formed by the cutting circular blade.

72. The spinal fixation kit of claim 70 wherein the fixation member includes a spacer element configured so as to be capable of being received in an intervertebral space between adjacent vertebrae.

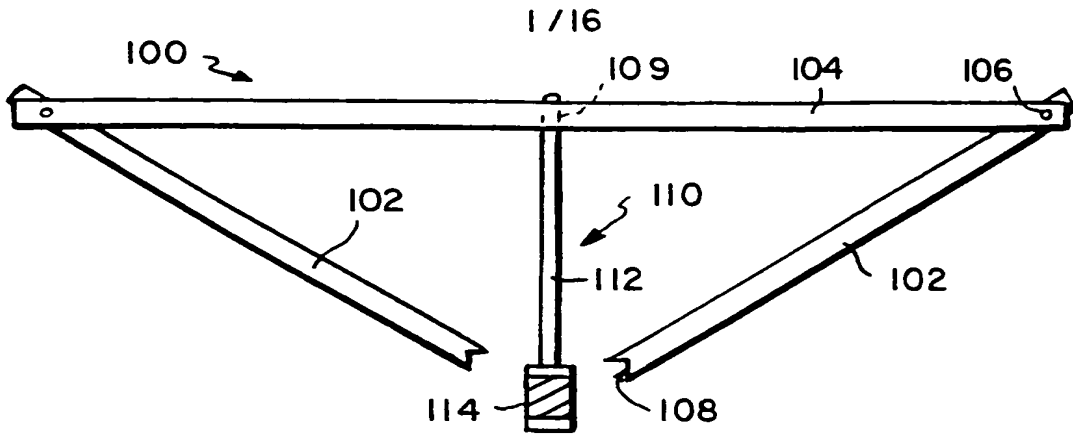


FIG. 1A

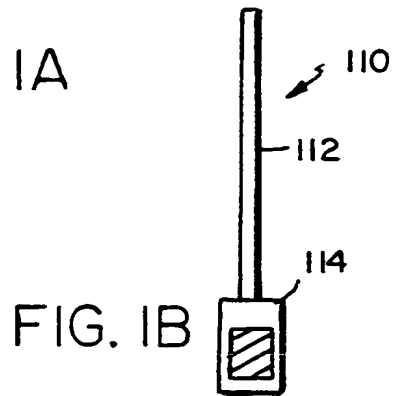


FIG. 1B

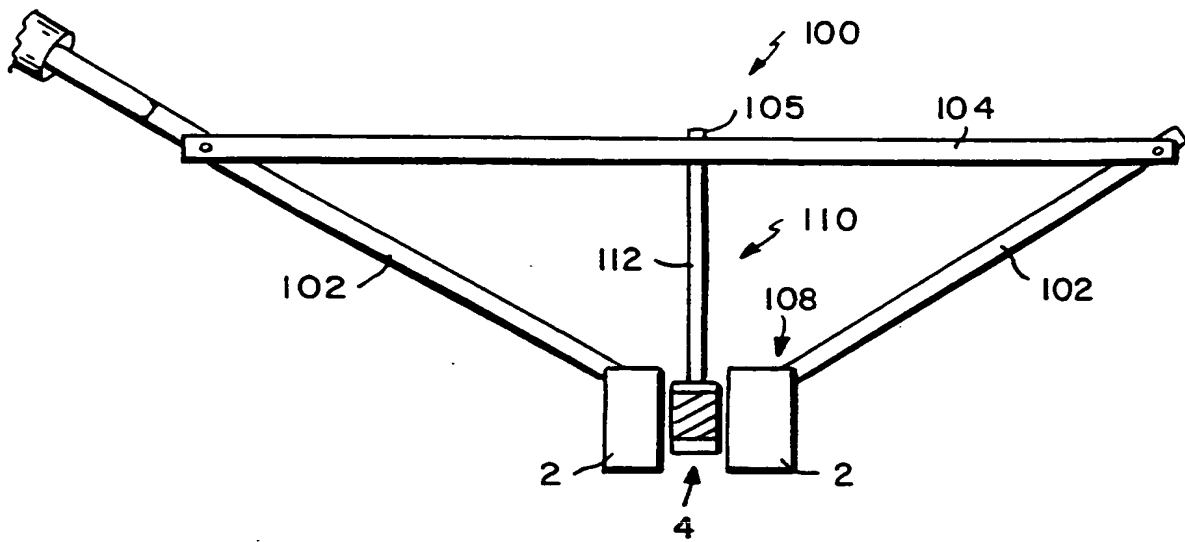


FIG. 2A

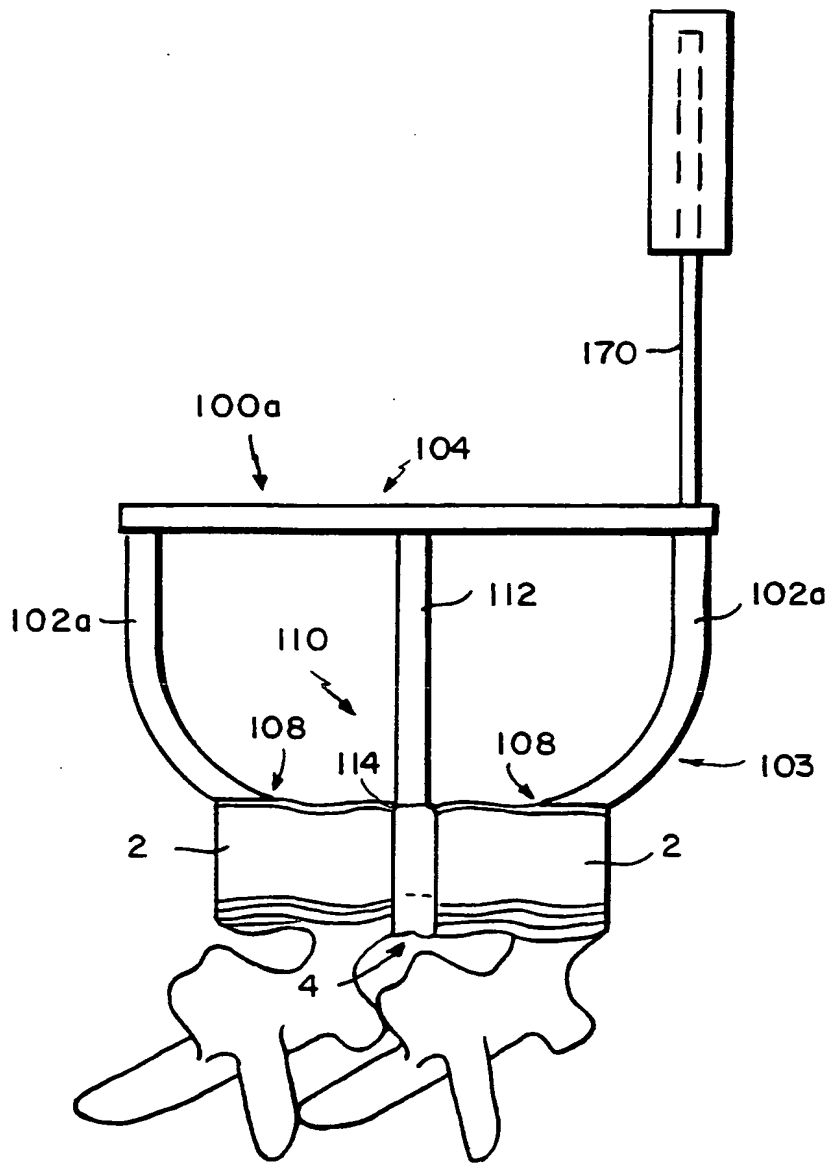


FIG. 2B

FIG. 3A

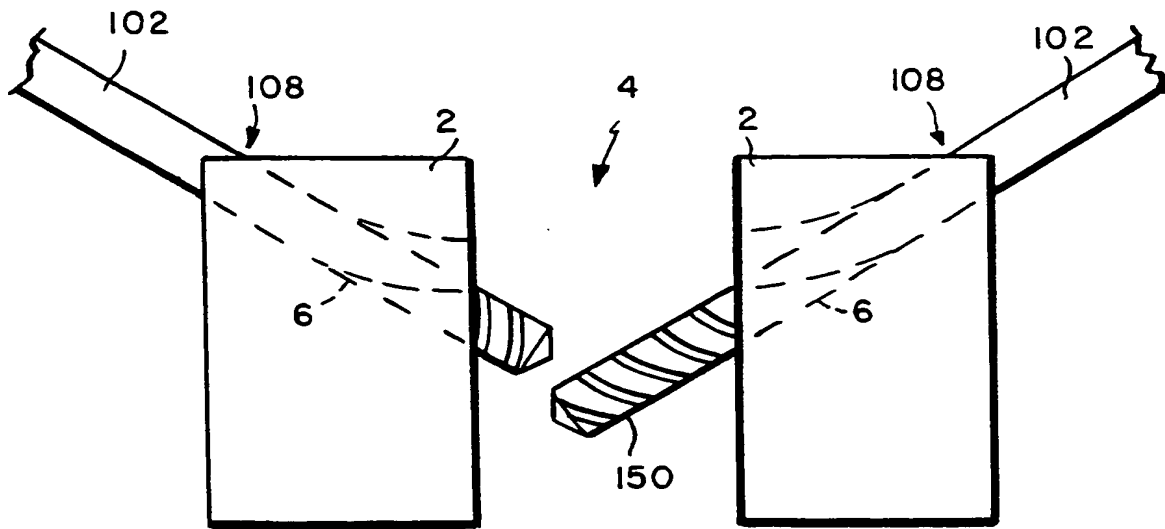
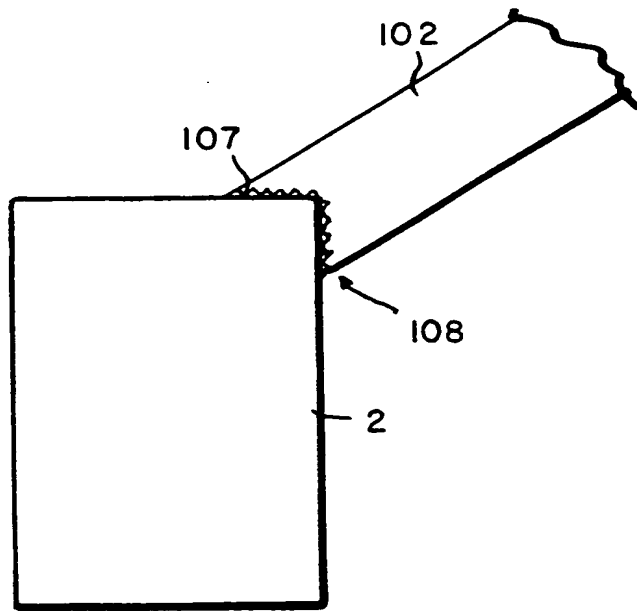


FIG. 3B

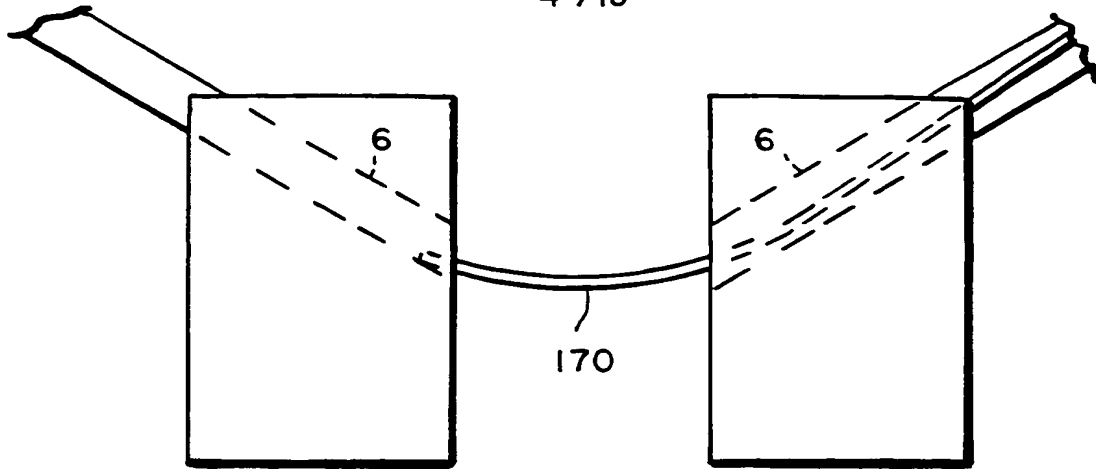


FIG. 3C

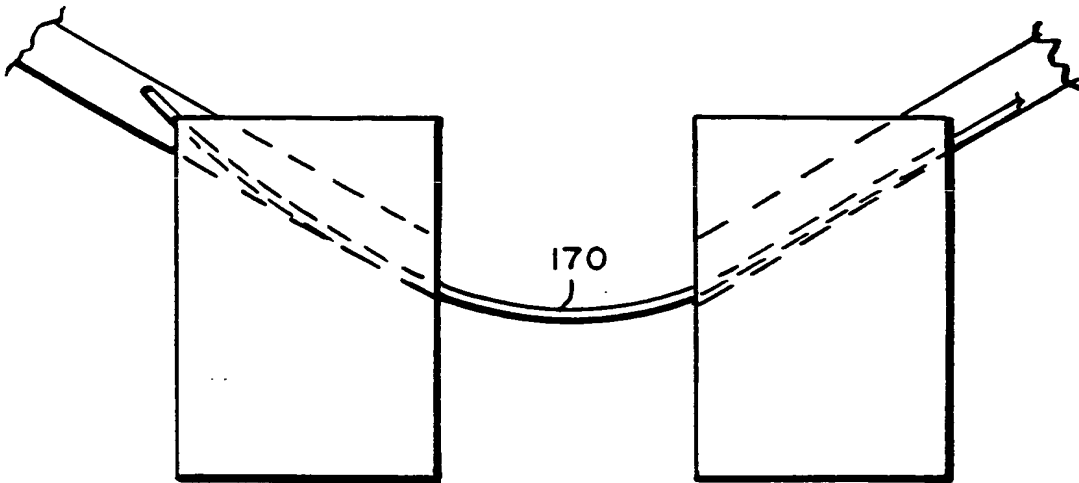


FIG. 3D

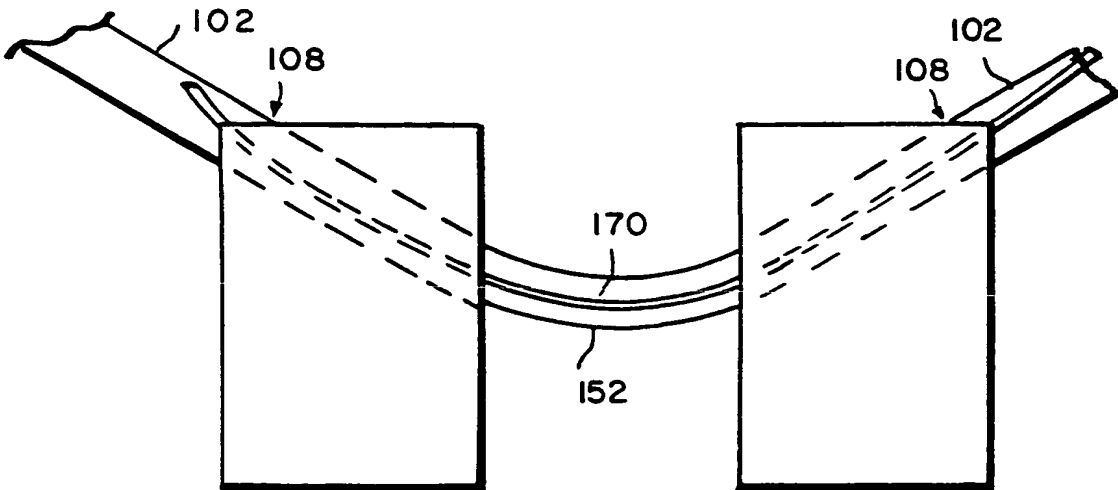


FIG. 3E

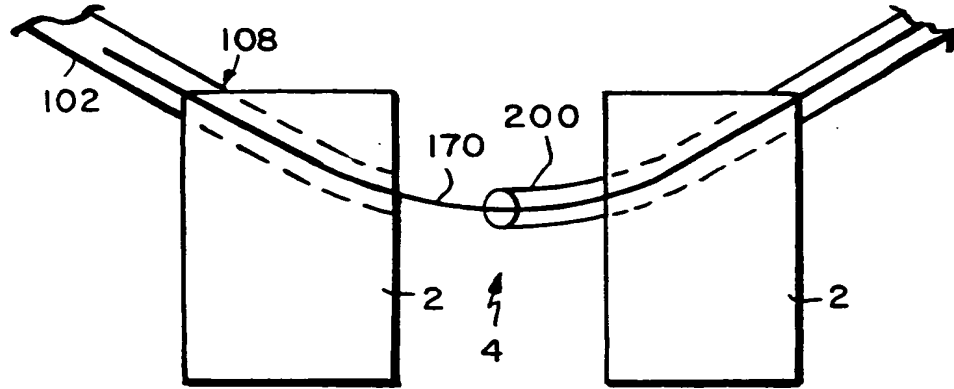


FIG. 4A

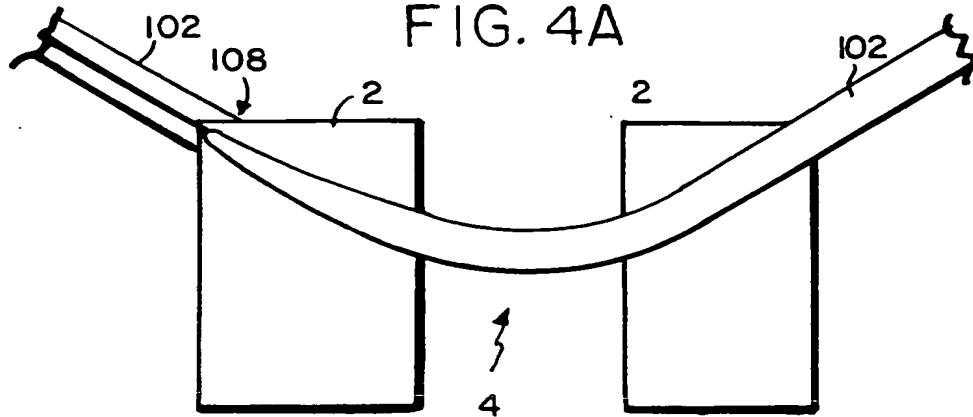


FIG. 4B

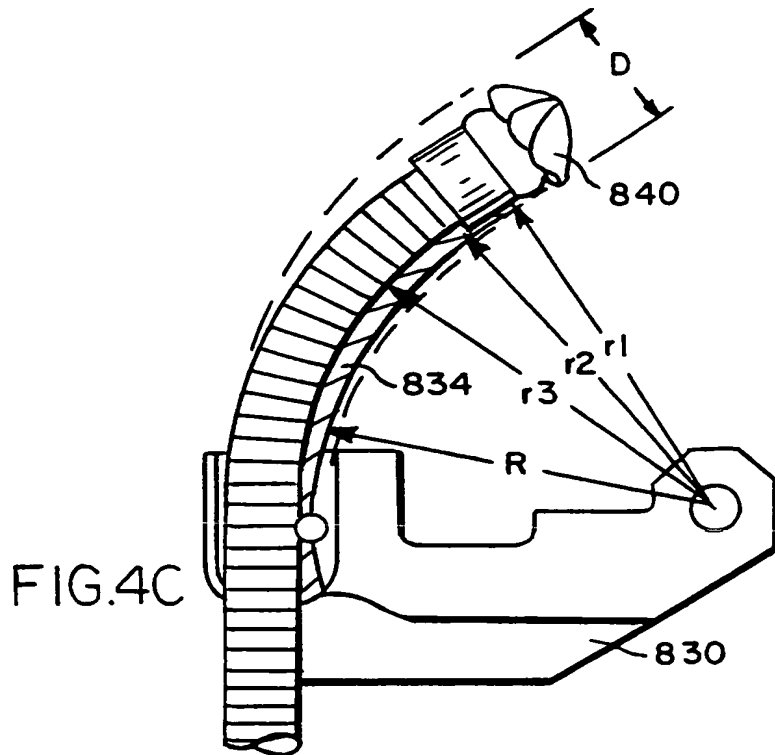


FIG. 4C

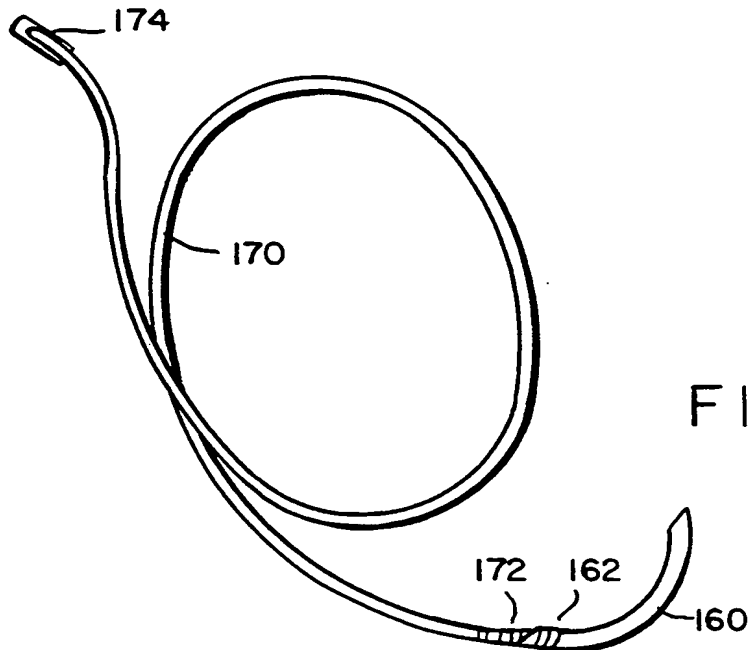


FIG. 5A

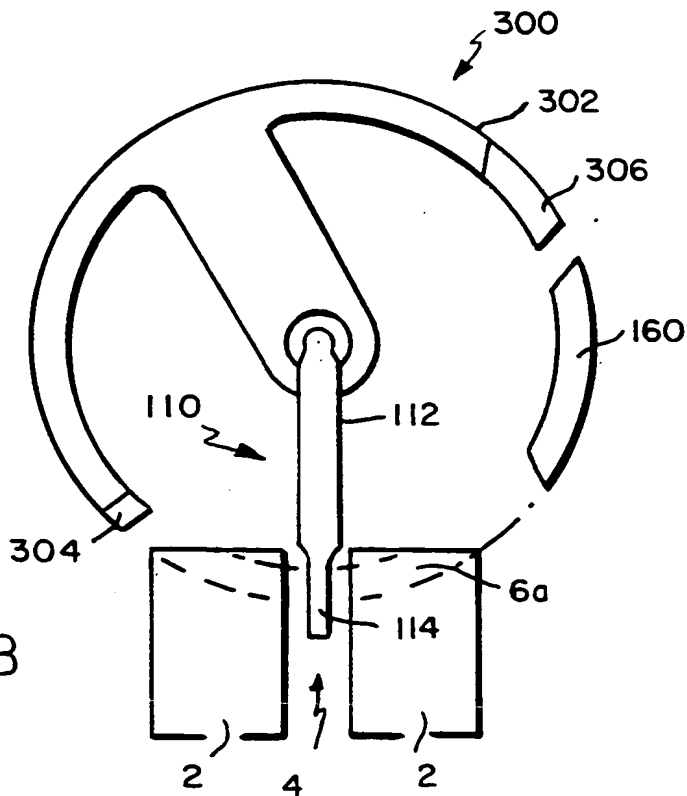


FIG. 5B

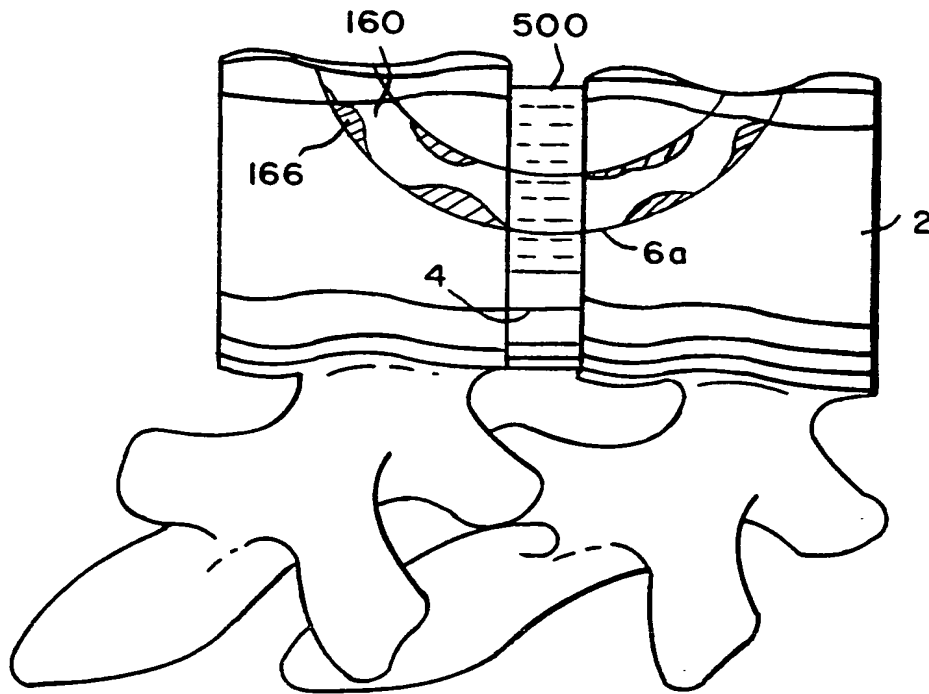


FIG. 6A

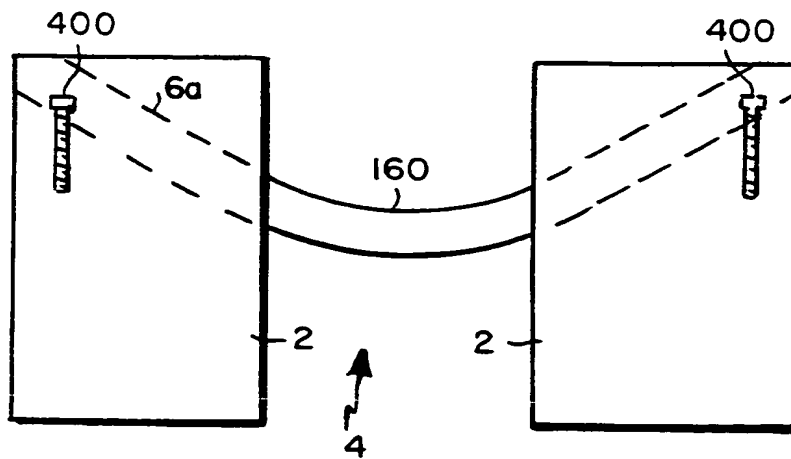


FIG. 6C

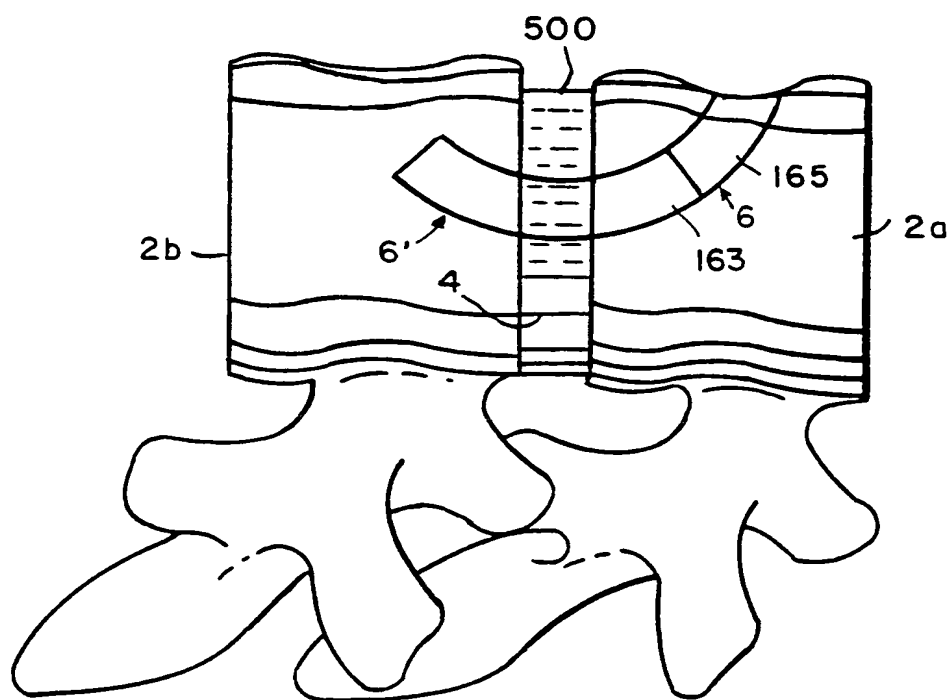


FIG. 6B

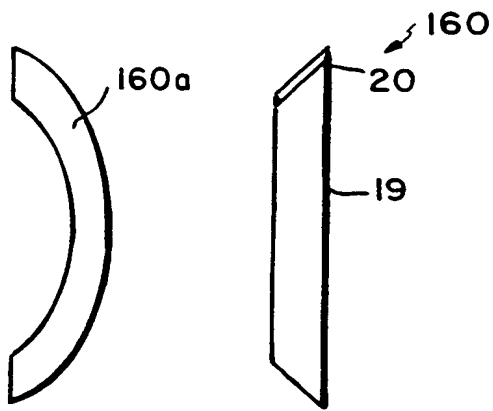


FIG. 7A FIG. 7B

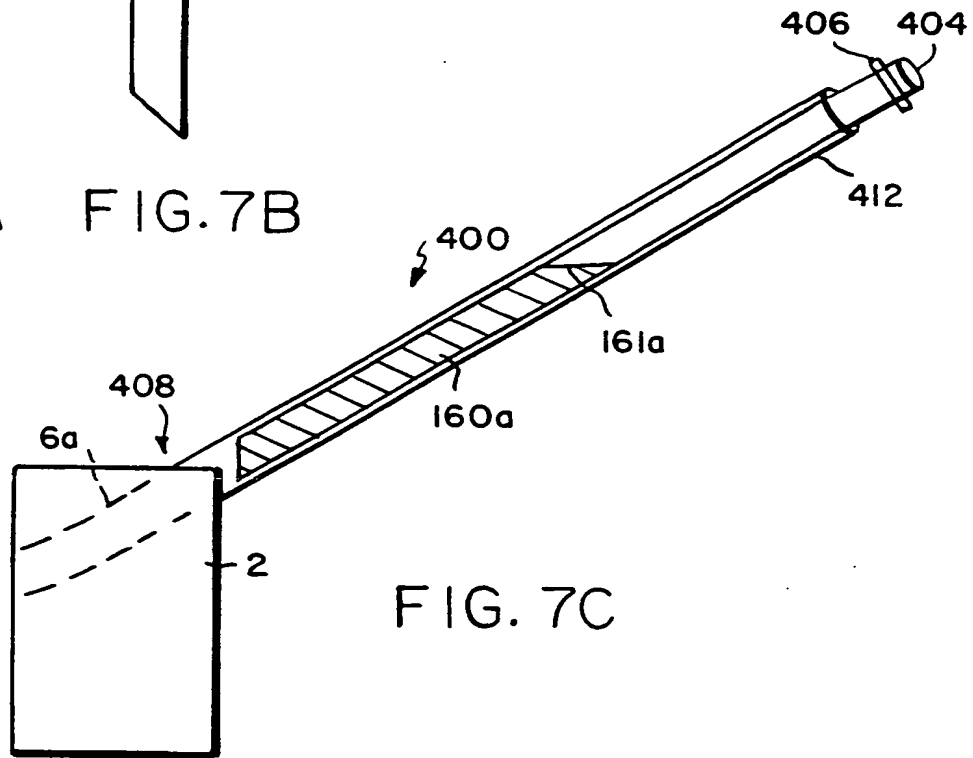


FIG. 7C

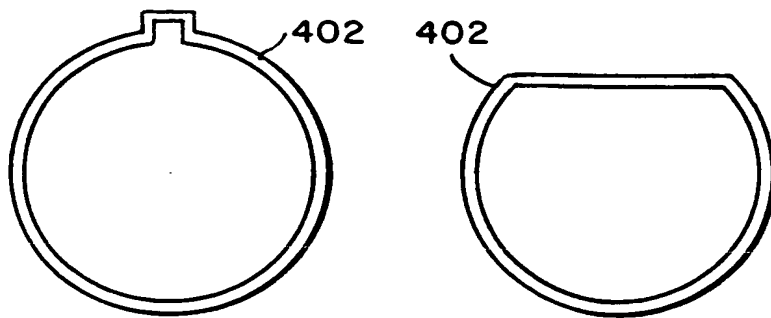


FIG. 8A

FIG. 8B

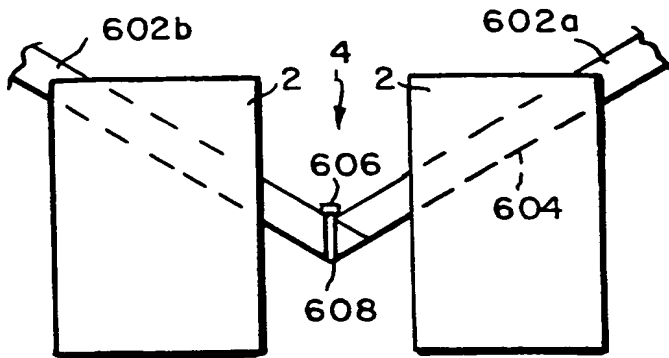


FIG. 9

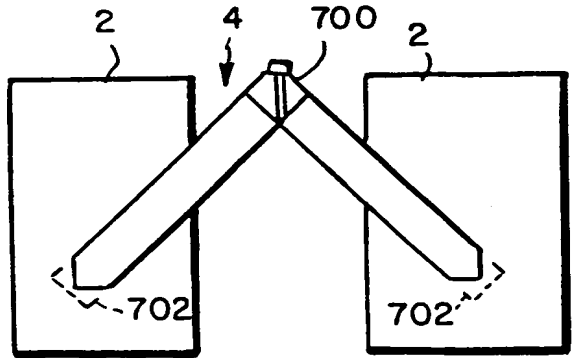


FIG. 10

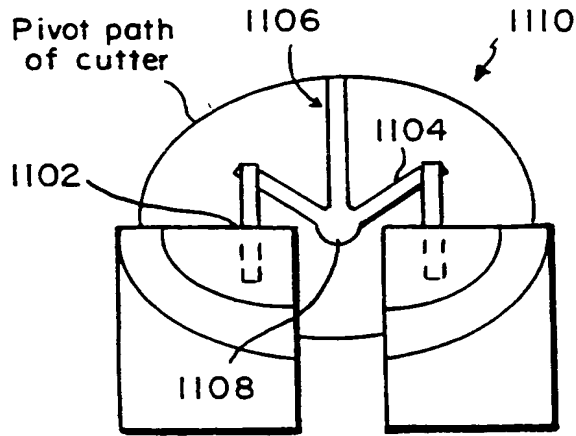


FIG. 11A

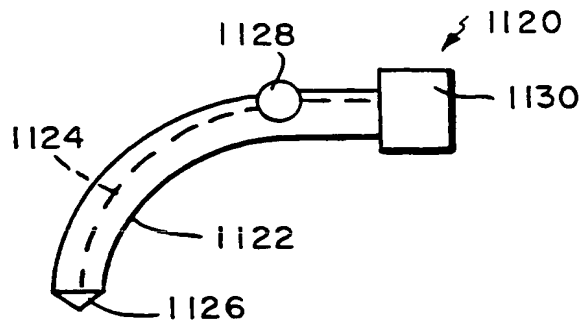


FIG. 11B

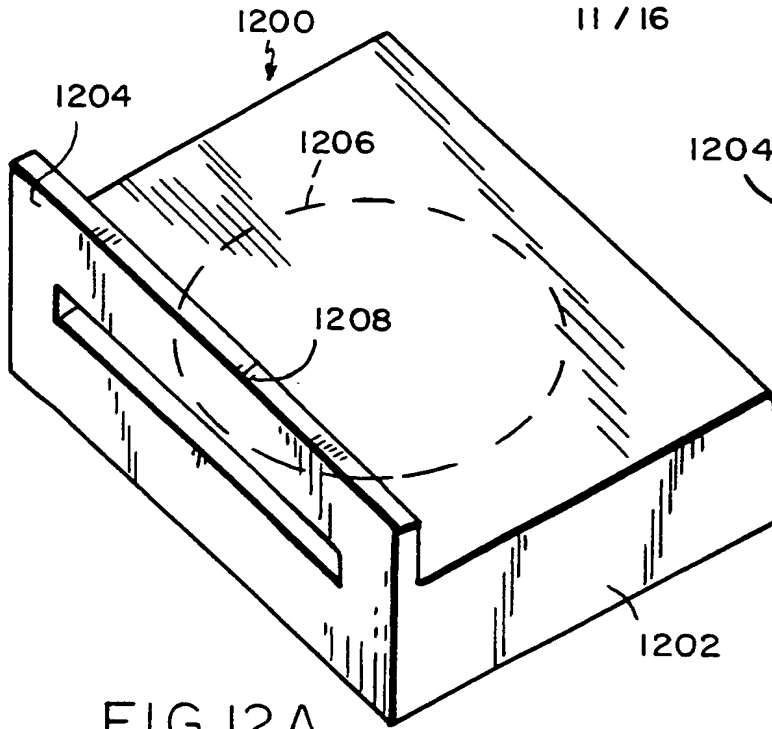


FIG. 12A

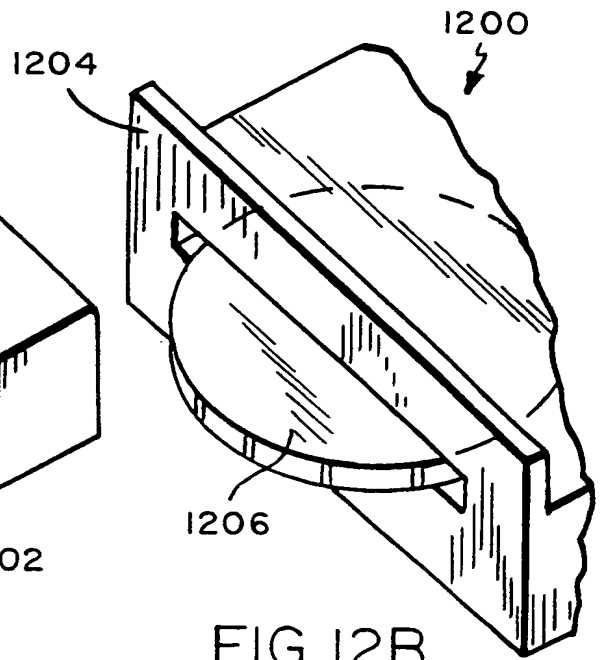


FIG. 12B

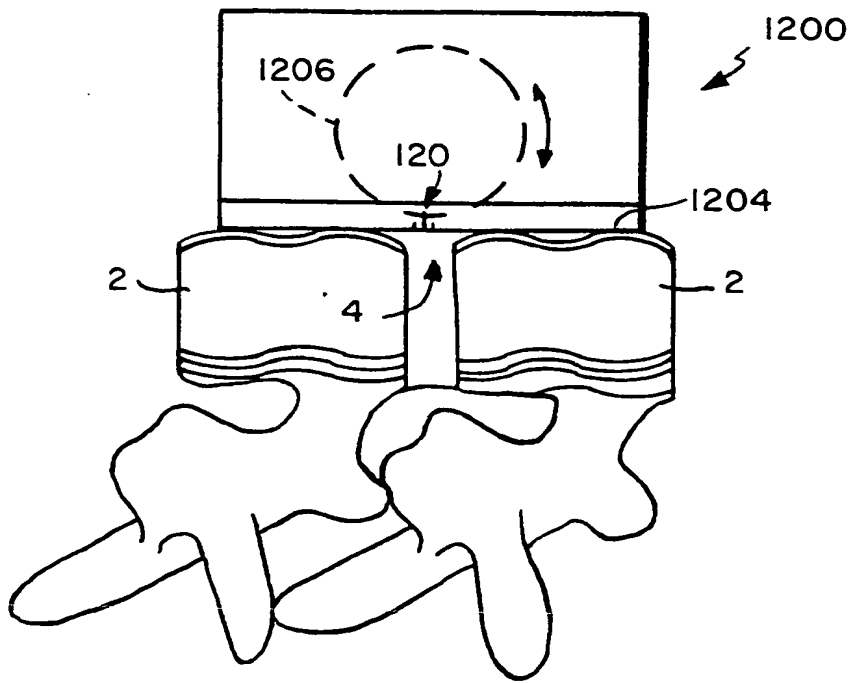


FIG. 12C

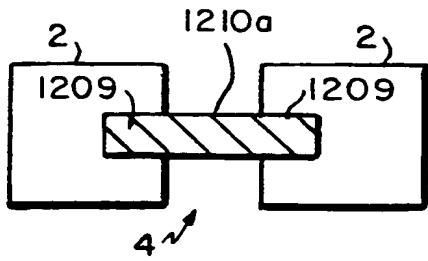


FIG. 12D

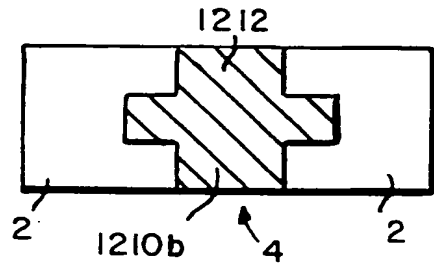


FIG. 12E

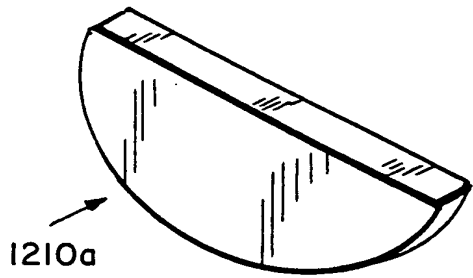


FIG. 12F

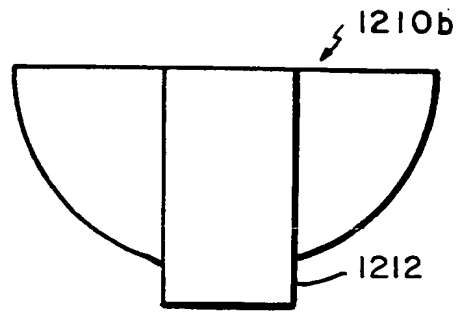


FIG. 12G

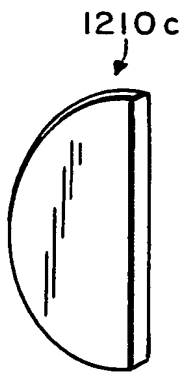


FIG. 12H



FIG. 12I

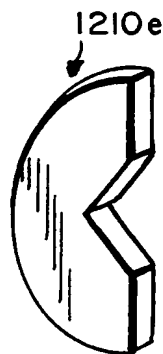


FIG. 12J

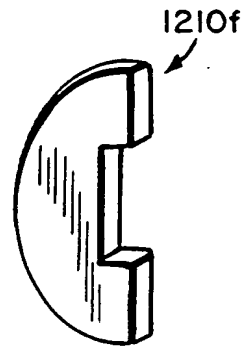


FIG. 12K

13/16

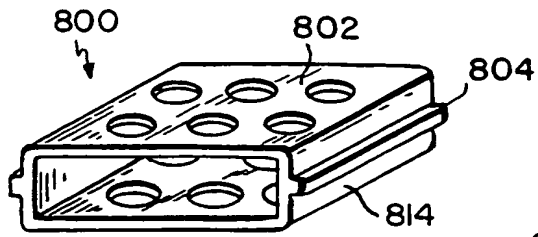


FIG. 13A

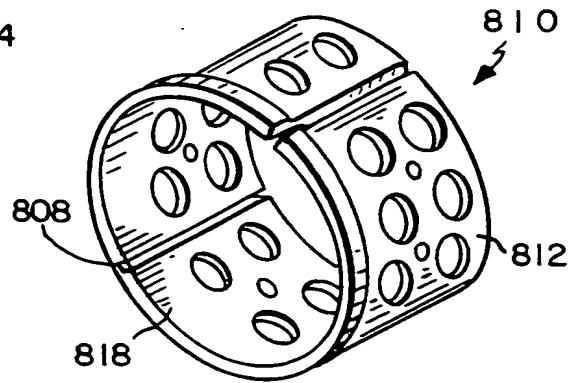


FIG. 13B

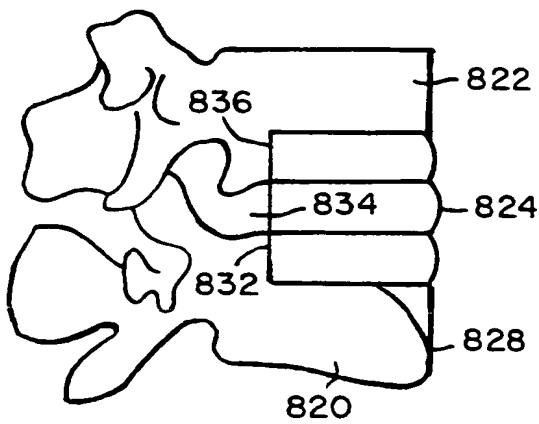


FIG. 13C

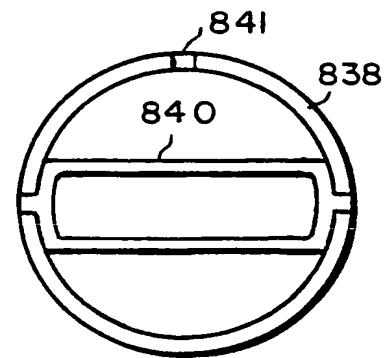


FIG. 13D

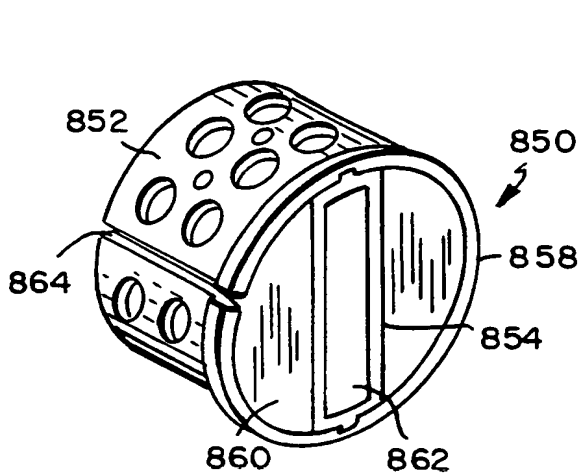


FIG. 13F

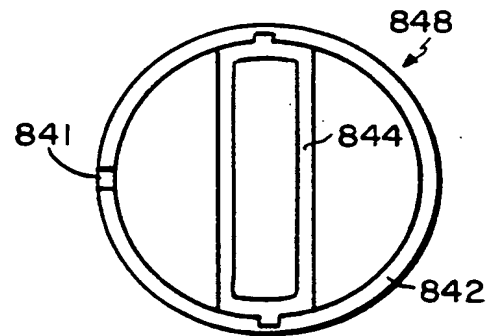


FIG. 13E

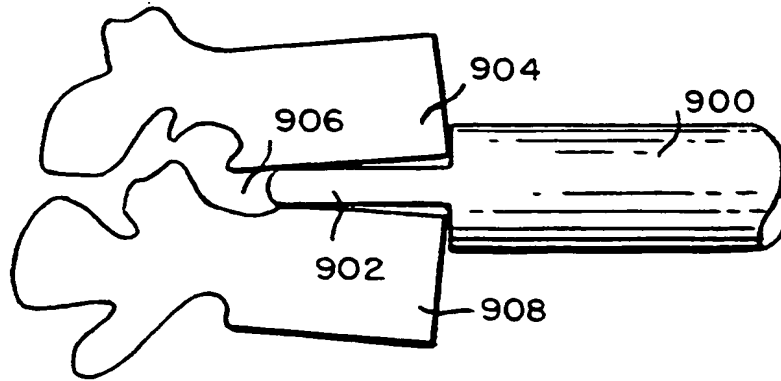


FIG. 14A

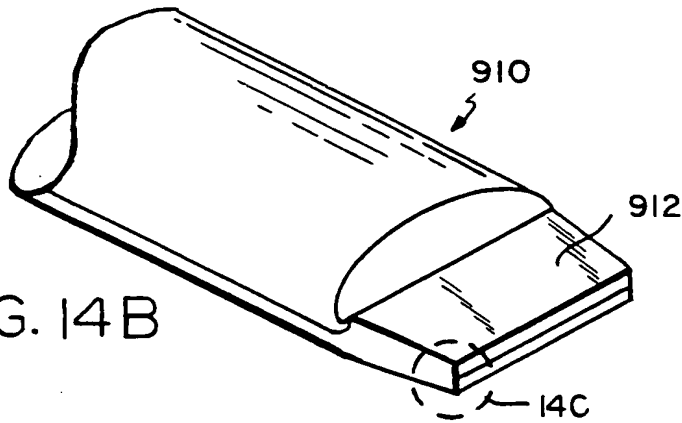


FIG. 14B

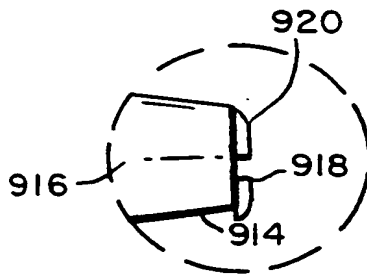


FIG. 14C

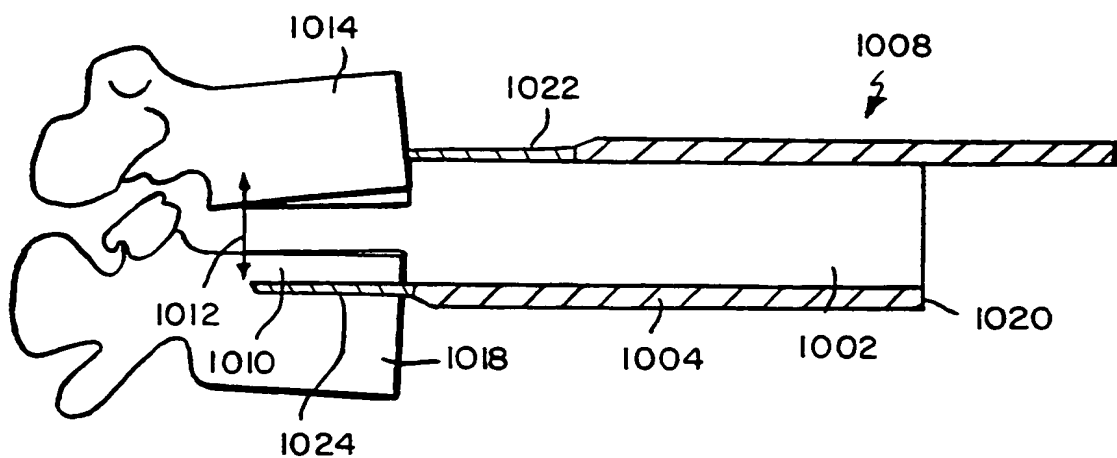


FIG. 15

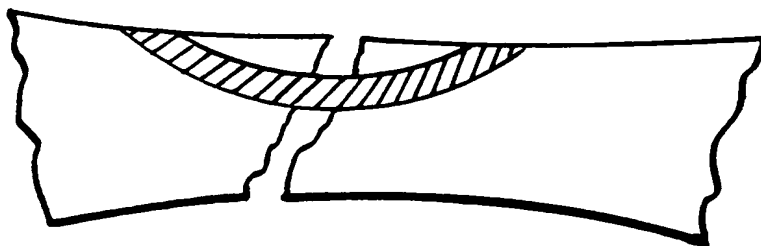


FIG. 16

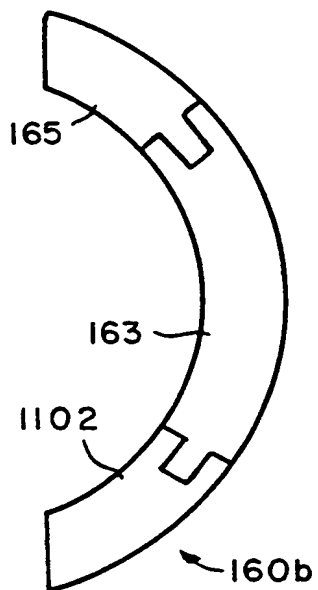


FIG. 17A

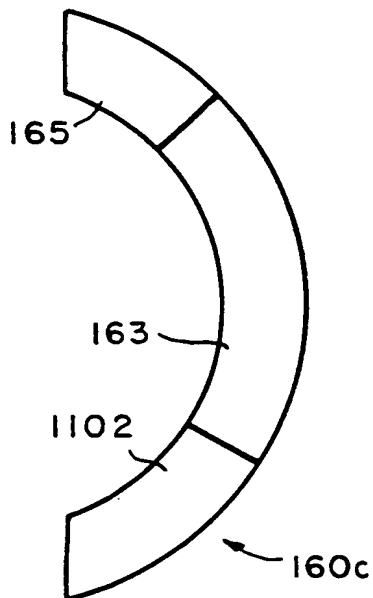


FIG. 17B

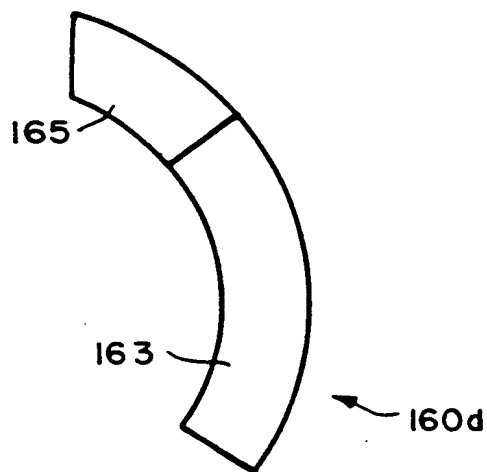


FIG. 17C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/12773

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-6, 34-38

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

PATENT COOPERATION TREATY

From the RECEIVING OFFICE

PCT

**NOTIFICATION OF THE INTERNATIONAL
APPLICATION NUMBER AND OF THE
INTERNATIONAL FILING DATE**

(PCT Rule 20.5(c))

To:

PETER F. CORLESS
DIKE, BRONSTEIN, ROBERTS & CUSHMAN, LLP
130 WATER STREET
BOSTON MA 02109

Date of mailing
(day/month/year) **16 JUN 2000**

Applicant's or agent's file reference
49386-PCT

IMPORTANT NOTIFICATION

International application No.
PCT/US00/12773

International filing date (day/month/year)
10 MAY 00

Priority date (day/month/year)
10 MAY 99

Applicant **HIGHGATE ORTHOPEDICS, INC.**

Title of the invention **SYSTEMS AND METHODS FOR SPINAL FIXATION**

1. The applicant is hereby notified that the international application has been accorded the international application number and the international filing date indicated above.

2. The applicant is further notified that the record copy of the international application:

was transmitted to the International Bureau on **16 JUN 2000**

has not yet been transmitted to the International Bureau for the reason indicated below and a copy of this notification has been sent to the International Bureau*:

because the necessary national security clearance has not yet been obtained.

because (reason to be specified):

* The International Bureau monitors the transmittal of the record copy by the receiving Office and will notify the applicant (with Form PCT/IB/301) of its receipt. Should the record copy not have been received by the expiration of 14 months from the priority date, the International Bureau will notify the applicant (Rule 22.1(c)).

3. FOREIGN TRANSMITTAL LICENSE INFORMATION

Completed by: *S. Barnes*

Additional license for foreign transmittal not required. This subject matter is covered by a license already granted on the equivalent U.S. national application. Refer to that license for information concerning its scope.

License for foreign transmittal not required. 37 CFR 5.11(e)(1) or 37 CFR 5.11(e)(2). However, a license may be required for additional subject matter. See 37 CFR 5.15(b).

Foreign transmittal license granted. 35 U.S.C. 184; 37 CFR 5.11 on **5-30-00** :
(date)

37 CFR 5.15(a)

37 CFR 5.15(b)

Name and mailing address of the receiving Office
Assistant Commissioner for Patents
Box PCT
Washington, D.C. 20231
Attn: RO/US
Facsimile No.

Authorized officer
Sonya D. Barnes
PCT/Internat'l Appl Processing Div
(703) 305-3665
Telephone No.

FC/WJD
9386-PCT
(7/995)

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING
SUBMISSION OR TRANSMITTAL
OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

CORLESS, Peter, F.
Dike, Bronstein, Roberts &
Cushman, LLP
130 Water Street
Boston, MA 02109
ETATS-UNIS D'AMERIQUE

JAN 03 2001
DIKE BRONSTEIN
ROBERTS CUSHMAN LLP

Date of mailing (day/month/year) 12 December 2000 (12.12.00)	
Applicant's or agent's file reference 49386-PCT	IMPORTANT NOTIFICATION
International application No. PCT/US00/12773	International filing date (day/month/year) 10 May 2000 (10.05.00)
International publication date (day/month/year) 16 November 2000 (16.11.00)	Priority date (day/month/year) 10 May 1999 (10.05.99)
Applicant HIGHGATE ORTHOPEDICS, INC. et al	

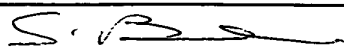
1. The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).

2. This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.

3. An asterisk(*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

4. The letters "NR" appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

Priority date	Priority application No.	Country or regional Office or PCT receiving Office	Date of receipt of priority document
10 May 1999 (10.05.99)	60/133,356	US	30 June 2000 (30.06.00)
28 Marc 2000 (28.03.00)	09/536,732	US	29 June 2000 (29.06.00)

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. (41-22) 740.14.35	Authorized officer  Simin Baharlou Telephone No. (41-22) 338.83.38
----------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

To:
CORLESS, Peter, F.
Dike, Bronstein, Roberts &
Cushman, LLP
130 Water Street
Boston, MA 02109
ETATS-UNIS D'AMERIQUE

RECEIVED
NOV 27 2000

DIKE BRONSTEIN
ROBERTS CUSHMAN

Date of mailing (day/month/year) 16 November 2000 (16.11.00)		IMPORTANT NOTICE	
Applicant's or agent's file reference 49386-PCT			
International application No. PCT/US00/12773	International filing date (day/month/year) 10 May 2000 (10.05.00)	Priority date (day/month/year) 10 May 1999 (10.05.99)	
Applicant HIGHGATE ORTHOPEDICS, INC. et al			

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:
AG,AU,DZ,KP,KR,US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:

AE,AL,AM,AP,AT,AZ,BA,BB,BG,BR,BY,CA,CH,CN,CR,CU,CZ,DE,DK,DM,EA,EE,EP,ES,FI,GB,GD,GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,MN,MW,MX,NO,NZ,OA,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,ZA,ZW
The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on 16 November 2000 (16.11.00) under No. WO 00/67651

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

<p>The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p>	<p>Authorized officer J. Zahra</p>
Facsimile No. (41-22) 740.14.35	Telephone No. (41-22) 338.83.38

The demand must be filed directly with the competent International Preliminary Examining Authority or, if two or more Authorities are with the one chosen by the applicant. The full name or two-letter code of that Authority may be indicated by the applicant on the line

IPEA/ US

PCT

CHAPTER II

DEMAND

under Article 31 of the Patent Cooperation Treaty:
The undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty and hereby elects all eligible States (except where otherwise indicated).

For International Preliminary Examining Authority use only

Identification of IPEA		Date of receipt of DEMAND	
Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION		Applicant's or agent's file reference 49386-PCT	
International application No. PCT/US00/12773	International filing date (day/month/year) 10 May 2000 (10.05.00)	(Earliest) Priority date (day/month/year) 10 May 1999 (10.05.99)	
Title of invention SYSTEMS AND METHODS FOR SPINAL FIXATION			
Box No. II APPLICANT(S)			
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) HIGHGATE ORTHOPEDICS, INC. One Walnut Street Boston, Massachusetts 02109 United States of America		Telephone No.: (617) 305-4140	
		Facsimile No.: (617) 305-4144	
		Teleprinter No.:	
State (that is, country) of nationality: US		State (that is, country) of residence: US	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) CARL, Allen 308 Highgate Drive Slingerlands, New York 12159 United States of America			
State (that is, country) of nationality: US		State (that is, country) of residence: US	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) HART, Rickey D. 11 Hillsdale Road Plainville, Massachusetts 02762 United States of America			
State (that is, country) of nationality: US		State (that is, country) of residence: US	
<input checked="" type="checkbox"/> Further applicants are indicated on a continuation sheet.			

Continuation of Box No. II APPLICANT(S)

If none of the following sub-boxes is used, this sheet is not to be included in the demand.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

WINKLER, Josef K.
2318 Gring Drive
Reading, Pennsylvania 19609
United States of America

State *(that is, country)* of nationality:

US

State *(that is, country)* of residence:

US

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

Further applicants are indicated on another continuation sheet.

Box No. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The following person is agent common representative
 and has been appointed earlier and represents the applicant(s) also for international preliminary examination.
 is hereby appointed and any earlier appointment of (an) agent(s) /common representative is hereby revoked.
 is hereby appointed, specifically for the procedure before the International Preliminary Examining Authority, in addition to the agent(s)/common representative appointed earlier.

Name and address: *(Family name followed by given name; for a legal entity, full official
 The address must include postal code and name of country.)*

CORLESS, Peter F.
 Dike, Bronstein, Roberts & Cushman
 Intellectual Property Practice Group
 EDWARDS & ANGELL, LLP
 130 Water Street
 Boston, Massachusetts 02109
 United States of America

Telephone No.:
 (617) 523-3400

Facsimile No.:
 (617) 523-6440

Teleprinter No.:

Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No. IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION**Statement concerning amendments:***

1. The applicant wishes the international preliminary examination to start on the basis of:

the international application as originally filed.

the description as originally filed
 as amended under Article 34

the claims as originally filed
 as amended under Article 19 (together with any accompanying statement)
 as amended under Article 34

the drawings as originally filed
 as amended under Article 34

2. The applicant wishes any amendment to the claims under Article 19 to be considered as reversed.

3. The applicant wishes the start of the international preliminary examination to be postponed until the expiration of 20 months from the priority date unless the International Preliminary Examining Authority receives a copy of any amendments made under Article 19 or a notice from the applicant that he does not wish to make such amendments (Rule 69.1(d)). *(This check-box may be marked only where the time limit under Article 19 has not yet expired.)*

* Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

Language for the purposes of international preliminary examination: English

- which is the language in which the international application was filed.
 which is the language of a translation furnished for the purposes of international search.
 which is the language of publication of the international application.
 which is the language of the translation (to be) furnished for the purposes of international preliminary examination.

Box No. V ELECTION OF STATES

The applicant hereby elects all eligible States *(that is, all States which have been designated and which are bound by Chapter II of the PCT)*

excluding the following States which the applicant wishes not to elect:

Box No. VI CHECK LIST

The demand is accompanied by the following elements, in the language referred to in Box No. IV, for the purposes of international preliminary examination:

- | | | |
|-------------------------------------------------------------------------|---|--------|
| 1. translation of international application | : | sheets |
| 2. amendments under Article 34 | : | sheets |
| 3. copy (or where required, translation) of amendments under Article 19 | : | sheets |
| 4. copy (or, where required, translation) of statement under Article 19 | : | sheets |
| 5. letter | : | sheets |
| 6. other (<i>specify</i>) | : | sheets |

For International Preliminary Examining Authority use only

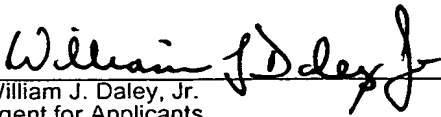
received	not received
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

The demand is also accompanied by the item(s) marked below:

- | | |
|------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| 1. <input checked="" type="checkbox"/> fee calculation sheet | 4. <input type="checkbox"/> statement explaining lack of signature |
| 2. <input type="checkbox"/> separate signed power of attorney | 5. <input type="checkbox"/> nucleotide and or amino acid sequence listing in computer readable form |
| 3. <input type="checkbox"/> copy of general power of attorney; reference number, if any: | 6. <input type="checkbox"/> other (<i>specify</i>): |

Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand).


 William J. Daley, Jr.
 Agent for Applicants

For International Preliminary Examining Authority use only

1. Date of actual receipt of DEMAND:

2. Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):

3. The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 or 5, below, does not apply.

The applicant has been informed accordingly.

4. The date of receipt of the demand is WITHIN the period of 19 months from the priority date as extended by virtue of Rule 80.5.

5. Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSSED pursuant to Rule 82.

For International Bureau use only

Demand received from IPEA on:

PCT

FEE CALCULATION SHEET

Annex to the Demand for international preliminary examination

International application No. PCT/US00/12773	For International Preliminary Examining Authority use only Date stamp of the IPEA		
Applicant's or agent's file reference 49386-PCT			
Applicant HIGHGATE ORTHOPEDICS, INC.			
Calculation of prescribed fees			
1. Preliminary examination fee	490.00 <input type="checkbox"/> P		
2. Handling fee (<i>Applicants from certain States are entitled to a reduction of 75% of the handling fee. Where the applicant is (or all applicants are) so entitled, the amount to be entered at H is 25% of the handling fee.</i>)	153.00 <input type="checkbox"/> H		
3. Total of prescribed fees Add the amounts entered at P and H and enter total in the TOTAL box	<table border="1" style="margin-left: auto; margin-right: auto;"> <tr> <td style="text-align: center; padding: 5px;">643.00</td> </tr> <tr> <td style="text-align: center; padding: 5px;">TOTAL</td> </tr> </table>	643.00	TOTAL
643.00			
TOTAL			
Mode of Payment			
<input type="checkbox"/> authorization to charge deposit account with the IPEA (see below)	<input type="checkbox"/> cash		
<input checked="" type="checkbox"/> cheque	<input type="checkbox"/> revenue stamps		
<input type="checkbox"/> postal money order	<input type="checkbox"/> coupons		
<input type="checkbox"/> bank draft	<input type="checkbox"/> other (<i>specify</i>):		
Deposit Account Authorization (<i>this mode of payment may not be available at all IPEAs</i>)			
The IPEA/ <u>US</u> <input type="checkbox"/> is hereby authorized to charge the total fees indicated above to my deposit account.			
<input checked="" type="checkbox"/> (<i>this check-box may be marked only if the conditions for deposit accounts of the IPEA so permit</i>) is hereby authorized to charge any deficiency or credit any overpayment in the total fees indicated above to my deposit account.			
04-1105 Deposit Account Number	07 December 2000 Date (day/month/year)		
Signature <u><i>William J. Daley</i></u>			

PFC
WJD

PATENT COOPERATION TREATY

MAY 03 2001

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

WRITTEN OPINION

(PCT Rule 66)

To:

PETER F. CORLESS
DIKE, BRONSTEIN, ROBERTS
& CUSHMAN, LLP
130 WATER STREET
BOSTON, MA 02109

Date of Mailing
(day/month/year) **30 APR 2001**

Applicant's or agent's file reference 49386-PCT		REPLY DUE within TWO months from the above date of mailing
International application No. PCT/US00/12773	International filing date (day/month/year) 10 MAY 2000	Priority date (day/month/year) 10 MAY 1999
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61B 17/70 and US Cl.: 606/61		
Applicant HIGHGATE ORTHOPEDICS, INC.		

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I Basis of the opinion
- II Priority
- III Non-establishment of opinion with regard to novelty, inventive step or industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis. For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 10 SEPTEMBER 2001

WRITTEN OPINION
Edwards & Angell LLP
Dike, Bronstein, Roberts & Cushman
130 Water St. Boston, MA 02108
Date Rec'd. 5/13
Docketed For May 30 - June 30, 2001
By EMT
Approved

Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer <i>[Signature]</i> L. GENE MANCENE
Facsimile No. (703) 305-3230	Telephone No. (703) 308-2696

I. Basis of the opinion

1. With regard to the elements of the international application:*

the international application as originally filed

the description:

pages 1-35 , as originally filed
 pages NONE , filed with the demand
 pages NONE , filed with the letter of _____

the claims:

pages 36-48 , as originally filed
 pages NONE , as amended (together with any statement) under Article 19
 pages NONE , filed with the demand
 pages NONE , filed with the letter of _____

the drawings:

pages 1-16 , as originally filed
 pages NONE , filed with the demand
 pages NONE , filed with the letter of _____

the sequence listing part of the description:

pages NONE , as originally filed
 pages NONE , filed with the demand
 pages NONE , filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

the language of publication of the international application (under Rule 48.3(b)).

the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

contained in the international application in printed form.

filed together with the international application in computer readable form.

furnished subsequently to this Authority in written form.

furnished subsequently to this Authority in computer readable form.

The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

the description, pages NONE

the claims, Nos. NONE

the drawings, sheets/fig NONE

5. This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".

WRITTEN OPINION

International application No.

PCT/US00/12773

IV. Lack of unity of invention

1. In response to the invitation (Form PCT/IPEA/405) to restrict or pay additional fees the applicant has:

- restricted the claims.
- paid additional fees.
- paid additional fees under protest.
- neither restricted nor paid additional fees.

2. This Authority found that the requirement of unity of invention is not complied with for the following reasons and chose, according to Rule 68.1 not to invite the applicant to restrict or pay additional fees:

3. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this opinion:

- all parts.
- the parts relating to claims Nos. 1-6 and 34-38.

WRITTEN OPINION

International application No.

PCT/US00/12773

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims <u>4</u>	YES
	Claims <u>1-3, 5, 6 and 34-38</u>	NO
Inventive Step (IS)	Claims <u>4</u>	YES
	Claims <u>1-3, 5, 6 and 34-38</u>	NO
Industrial Applicability (IA)	Claims <u>1-6, 34 and 38</u>	YES
	Claims <u>35 and 36</u>	NO

2. citations and explanations

Claims 1-3, 5, 6 and 34-38 lack novelty under PCT Article 33(2) as being anticipated by KUSLICH. As depicted in Fig. 1, Kuslich teaches a spinal fixation device comprising a rod 12, bone screws 14 and locking caps 26. Bone screws 14 are inserted into preformed apertures 50 to hold rod 12 within slots 22 and 24. Locking caps 26 lock the rod into engagement with the screws 14.

Rod 12 is disclosed as possibly being constructed of titanium.

Claims 35 and 36 lack(s) industrial applicability as defined by PCT Article 33(4). Claim 35 requires a "mammalian spine" as part of the claimed invention which is improper.

Claim 4 meets the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method for stabilizing adjacent vertebrae of a spine, comprising implanting an arcuate fixation member between the vertebrae and wherein the fixation member is the sole apparatus employed to affix the vertebrae.

----- NEW CITATIONS -----

NONE

WRITTEN OPINION

International application No.

PCT/US00/12773

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 4 is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claim is indefinite for the following reason(s): "apparatus" should be deleted from line 1.

WRITTEN OPINION

International application No.

PCT/US00/12773

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: PETER F. CORLESS
DIKE, BRONSTEIN, ROBERTS
& CUSHMAN, LLP
130 WATER STREET
BOSTON, MA 02109

PCT RECEIVED

NOTIFICATION OF TRANSMITTAL OF
INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

OCT 22 2001

(PCT Rule 71.1)

Date of Mailing
(day/month/year)

12 OCT 2001

Applicant's or agent's file reference
49386-PCT

IMPORTANT NOTIFICATION

International application No.
PCT/US00/12773

International filing date (day/month/year)
10 MAY 2000

Priority Date (day/month/year)
10-MAY 1999

Applicant
HIGHGATE ORTHOPEDICS, INC.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US
Commissioner of Patents and Trademarks
Box 1CT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

L. GENE MANCENE

Diane Smith f

Telephone No. (703) 308-2696

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 49386-PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/116)	
International application No. PCT/US00/12773	International filing date (day/month/year) 10 MAY 2000	Priority date (day/month/year) 10 MAY 1999
International Patent Classification (IPC) or national classification and IPC IPC(7): A61B 17/70 and US Cl.: 606/61		
Applicant HIGHGATE ORTHOPEDICS, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets.

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I Basis of the report
- II Priority
- III Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

Date of submission of the demand 07 DECEMBER 2000	Date of completion of this report 23 AUGUST 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer L. GENE MANCENE <i>Diane Smith f</i>
Facsimile No. (703) 305-3230	Telephone No. (703) 308-8620

I. Basis of the report

1. With regard to the elements of the international application:*

 the international application as originally filed the description:pages 1-35 , as originally filedpages NONE , filed with the demandpages NONE , filed with the letter of _____ the claims:pages 36-48 , as originally filedpages NONE , as amended (together with any statement) under Article 19pages NONE , filed with the demandpages NONE , filed with the letter of _____ the drawings:pages 1-16 , as originally filedpages NONE , filed with the demandpages NONE , filed with the letter of _____ the sequence listing part of the description:pages NONE , as originally filedpages NONE , filed with the demandpages NONE , filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

 the language of a translation furnished for the purposes of international search (under Rule 23.1(b)). the language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

 contained in the international application in printed form. filed together with the international application in computer readable form. furnished subsequently to this Authority in written form. furnished subsequently to this Authority in computer readable form. The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4. The amendments have resulted in the cancellation of: the description, pages NONE the claims, Nos. NONE the drawings, sheets/fig NONE5. This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

**Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

IV. Lack of unity of invention

1. In response to the invitation (Form PCT/IPEA/405) to restrict or pay additional fees the applicant has:

- restricted the claims.
 paid additional fees.
 paid additional fees under protest.
 neither restricted nor paid additional fees.

2. This Authority found that the requirement of unity of invention is not complied with for the following reasons and chose, according to Rule 68.1 not to invite the applicant to restrict or pay additional fees:

3. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this opinion:

- all parts.
 the parts relating to claims Nos. 1-6 and 34-38.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/12773

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**I. statement**

Novelty (N)	Claims	<u>4</u>	YES
	Claims	<u>1-3, 5, 6 and 34-38</u>	NO
Inventive Step (IS)	Claims	<u>4</u>	YES
	Claims	<u>1-3, 5, 6 and 34-38</u>	NO
Industrial Applicability (IA)	Claims	<u>1-6, 34 and 38</u>	YES
	Claims	<u>35 and 36</u>	NO

2. citations and explanations (Rule 70.7)

Claims 1-3, 5, 6 and 34-38 lack novelty under PCT Article 33(2) as being anticipated by KUSLICH. As depicted in Fig. 1, Kuslich teaches a spinal fixation device comprising a rod 12, bone screws 14 and locking caps 26. Bone screws 14 are inserted into preformed apertures 50 to hold rod 12 within slots 22 and 24. Locking caps 26 lock the rod into engagement with the screws 14.

Rod 12 is disclosed as possibly being constructed of titanium.

Claims 35 and 36 lack(s) industrial applicability as defined by PCT Article 33(4). Claim 35 requires a "mammalian spine" as part of the claimed invention which is improper.

Claim 4 meets the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method for stabilizing adjacent vertebrae of a spin, comprising implanting an arcuate fixation member between the vertebrae and wherein the fixation member is the sole apparatus employed to affix the vertebrae.

_____ NEW CITATIONS _____

NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/12773

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 4 is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claim is indefinite for the following reason(s): "apparatus" should be deleted from line 1.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

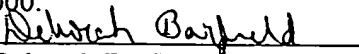
APPLICANT: Highgate Orthopedics, Inc.
INVENTORS: Allen Carl, Rickey D. Hart, and Josef K. Winkler
INT. APPLN. NO.: PCT/US00/12773
FILED: 10 May 2000
FOR: SYSTEMS AND METHODS FOR SPINAL FIXATION

BOX PCT
Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Attn: RO/US
Sonya D. Barnes
IAPD-PCT OPERATIONS

CERTIFICATE OF EXPRESS MAILING

I hereby certify that this correspondence and the documents referred to as enclosed therein are being deposited with the United States Postal Service on the date below in an envelope as "Express Mail" Post Office to Addressee" Mailing Label No. EL180585981US addressed to the Assistant Commissioner for Patents, Box PCT, Washington, DC, 20231 on July 6, 2000.


Deborah Barfield

SIR:

**RESPONSE TO INVITATION TO CORRECT
DEFECTS IN THE INTERNATIONAL APPLICATION**

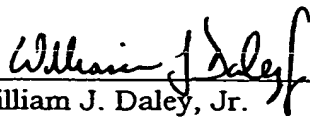
An Invitation to Correct Defects was mailed on 16 June 2000 for the above-referenced international application.

Accordingly, enclosed please find the executed page 5 of the PCT Request Form (signature page).

Please charge any fees that may be due in connection with this matter to Deposit Account 04-1105.

Respectfully submitted,

Date: 06 July 2000


William J. Daley, Jr.
(Reg. 35,487)
DIKE BRONSTEIN ROBERTS &
CUSHMAN, LLP
130 Water Street
Boston, MA 02109
617/523-3400

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: PETER F. CORLESS
 DIKE, BRONSTEIN, ROBERTS & CUSHMAN, LLP
 130 WATER STREET
 BOSTON, MASSACHUSETTS 02109

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

	Date of Mailing (day/month/year) 17 OCT 2000
Applicant's or agent's file reference 49386-PCT	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/US00/12773	International filing date (day/month/year) 10 MAY 2000
Applicant HIGHGATE ORTHOPEDICS, INC.	

1. The applicant is hereby notified that the international search report has been established and is transmitted herewith.
- Filing of amendments and statement under Article 19:**
 The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):
- When?** The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompanying sheet.
- Where?** Directly to the International Bureau of WIPO
 34, chemin des Colombettes
 1211 Geneva 20, Switzerland
 Facsimile No.: (41-22) 740.14.35
- For more detailed instructions, see the notes on the accompanying sheet.**
2. The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.
3. **With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:**
- the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.
4. **Further action(s):** The applicant is reminded of the following:
- Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 *bis* 1 and 90 *bis* 3, respectively, before the completion of the technical preparations for international publication.
- Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).
- Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer MICHAEL PRIDDY
Facsimile No. (703) 305-3230	Telephone No. (703) 308-8620

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 49386-PCT	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/US00/12773	International filing date (<i>day/month/year</i>) 10 MAY 2000	(Earliest) Priority Date (<i>day/month/year</i>) 10 MAY 1999
Applicant HIGHGATE ORTHOPEDICS, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:

contained in the international application in written form.

filed together with the international application in computer readable form.

furnished subsequently to this Authority in written form.

furnished subsequently to this Authority in computer readable form.

the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the

the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. Certain claims were found unsearchable (See Box I).

3. Unity of invention is lacking (See Box II).

4. With regard to the title,

the text is approved as submitted by the applicant.

the text has been established by this Authority to read as follows:

5. With regard to the abstract,

the text is approved as submitted by the applicant.

the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No. 3E

as suggested by the applicant.

because the applicant failed to suggest a figure.

because this figure better characterizes the invention.

None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/12773

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-6, 34-38

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

The technical features mentioned in the Abstract do not include a reference sign between parentheses (PCT Rule 8.1(d)).

The Abstract is too long (PCT Rule 8.1(b)). The Abstract must be less than 150 words, or 200 words when no figure is to be published.

NEW ABSTRACT

Featured are a method, and apparatus for fixing adjacent vertebrae of a spine that avoids the need, associated problems with prior cage or straight rod or screw systems. Methods, and apparatus of the invention utilize a new implant member (160), which preferably is arcuate. Preferred methods of the invention for stabilizing adjacent vertebrae of the spine, include steps of providing a positioning apparatus (100) including two guide sleeves (102), each guide sleeve (102) having a long axis, and locating the two guide sleeves (102) with respect to the adjacent vertebrae such that a vertex formed by the long axis of each guide sleeve (102) is located in the intervertebral space for the adjacent vertebrae. The method further includes forming an aperture in each of the adjacent vertebrae so that the implant (160) extends between the adjacent vertebrae, and through the intervertebral space.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/12773

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 17/70
US CL : 606/61

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/60, 61, 66, 69, 71, 72, 90, 105; 623/16.11, 17.11

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Extra Sheet.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,790,303 A (STEFFEE) 13 December 1988, Fig. 6.	1, 4-6, 34-38
X	US 5,591,235 A (KUSLICH) 07 January 1997, Figs. 1, 15 and 17.	1-3, 5, 6, 34-38
A	US 4,773,402 A (ASHER et al.) 27 September 1988, Fig. 11.	1-6, 34-38
A	US 5,415,661 A (HOLMES) 16 May 1995, Fig. 1A, 2 and 3.	1-6, 34-38
A	US 5,545,164 A (HOWLAND) 13 August 1996, Fig. 46.	1-6, 34-38
A	US 5,591,165 A (JACKSON) 07 January 1997, Fig. 9B.	1-6, 34-38

Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

14 SEPTEMBER 2000

Date of mailing of the international search report

17 OCT 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
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Authorized officer

MICHAEL PRIDDY

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/12773

B. FIELDS SEARCHED

Electronic data bases consulted (Name of data base and where practicable terms used):

EAST

Search Terms: (spinal ADJ fixation) AND arcuate

WEST

Search Terms: classification search of EPO and JPO within 606/60, 61, 66, 69, 71, 72, 90, 105.

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claims 1-6 and 34-38, drawn to a method, and apparatus for stabilizing/fixating adjacent vertebrae of a spine.

Group II, claims 7-33 and 39-46, drawn to a second method, and apparatus for stabilizing/fixating adjacent vertebrae of a spine.

Group III, claim 47, drawn to a method of facilitating a body union of two adjacent vertebrae.

Group IV, claims 48-59 and 64-68, drawn to a third method, and apparatus for stabilizing/fixating adjacent vertebrae of a spine.

Group V, claims 60-63 and 69-72, drawn to a fourth method, and apparatus for stabilizing/fixating adjacent vertebrae of a spine.

Groups I-V, the inventions listed as these groups do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each of the groups require distinct elements, and/or method steps not encompassed by each of the remaining groups.

1/c / WJD
(7/995)

PATENT COOPERATION TREATY

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ROBERTS CUSHMAN

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:
PETER F. CORLESS
DIKE, BRONSTEIN, ROBERTS & CUSHMAN, LLP
130 WATER STREET
BOSTON, MA 02109

NOTIFICATION OF RECEIPT
OF DEMAND BY COMPETENT INTERNATIONAL
PRELIMINARY EXAMINING AUTHORITY

(PCT Rules 59.3(e) and 61.1(b), first sentence
and Administrative Instructions, Section 601(a))

Date of mailing
(day/month/year) 23 JAN 01

Applicant's or agent's file reference
49386-PCT

IMPORTANT NOTIFICATION

International application No. PCT/US00/12773
International filing date (day/month/year) 10 MAY 00
Priority date (day/month/year) 10 MAY 99

Applicant
HIGHGATE ORTHOPEDICS, INC.

- The applicant is hereby notified that this International Preliminary Examining Authority considers the following date as the date of receipt of the demand for international preliminary examination of the international application:
07 December 2000 (07.12.00)
- That date of receipt is:
 - the actual date of receipt of the demand by this Authority (Rule 61.1(b)).
 - the actual date of receipt of the demand on behalf of this Authority (Rule 59.3(e)).
 - the date on which this Authority has, in response to the invitation to correct defects in the demand (Form PCT/IPEA/404), received the required corrections.
- ATTENTION:** That date of receipt is **AFTER** the expiration of 19 months from the priority date. Consequently, the election(s) made in the demand does (do) not have the effect of postponing the entry into the national phase until 30 months from the priority date (or later in some Offices) (Article 39(1)). Therefore, the acts for entry into the national phase must be performed within 20 months from the priority date (or later in some Offices) (Article 22). For details, see the *PCT Applicant's Guide*, Volume II.
 (If applicable) This notification confirms the information given by telephone, facsimile transmission or in person on:

- Only where paragraph 3 applies, a copy of this notification has been sent to the International Bureau.

Name and mailing address of the IPEA/
Assistant Commissioner for Patent
Box PCT
Washington, D.C. 20231 Attn:RO/US
Facsimile No. 703-305-3230

Authorized officer
Sonya D. Barnes
Telephone No. 703-305-3665

10/019265

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